

EXHIBIT A

<u>Case Name</u>	<u>Docket Number</u>
Bell, Patricia D. & Joseph	2:12cv06750
Blake, Patricia & Dale	2:12cv07901
Clark, Phyllis	2:12cv06481
Deaton, Sherry P.	2:12cv05774
DuBois, Virginia L. & Ronald	2:12cv08070
Friberg, Gloria & Henry	2:12cv06500
Gray, Ora Kay & Clarence Allen	2:12cv07251
Greenwood, Kassandra & Cody	2:12cv07889
Harrison, Lela B. & Larry	2:12cv06160
Hosbrook, Patricia	2:12cv07843
Jennings, Iris A. & Michael	2:12cv06217
Phelps, Teresa L.	2:12cv05790
Underwood, Martha A.	2:12cv06162

EXHIBIT B

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327
THIS DOCUMENT RELATES TO WAVE 5 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

EXPERT REPORT OF SCOTT GUELCHER, PH.D.

The opinions which are held and expressed to a reasonable degree of scientific certainty are as follows:

I. QUALIFICATIONS

Scott Guelcher, Ph.D.

I received my Bachelor's Degree in Chemical Engineering from Virginia Tech in 1992, my Master's Degree in Chemical Engineering from the University of Pittsburgh in 1996, and my Ph.D. in Chemical Engineering from Carnegie Mellon University in 1999. I completed my training as a Post-Doctoral Research Associate in Biomedical Engineering at Carnegie Mellon University in 2005.

I am currently a Professor of Chemical and Biomolecular Engineering at Vanderbilt University. Prior to my current appointment, I was an Associate Professor from 2012 through 2016 and an Assistant Professor from 2005 through 2012. I was recently appointed a Chancellor's Faculty Fellow for the period 2015 – 2017, and in December 2016 I was appointed the Director of the Vanderbilt Center for Bone Biology in the Department of Medicine at Vanderbilt University Medical Center. In 2016, I taught Design Projects (Spring) and Applied Chemical Kinetics (Fall). In 2017, I am teaching Design Projects (Spring).

My professional experience includes: Associate Scientist and Senior Associate Scientist at Bayer Corporation, Polyurethanes Division, in South Charleston, West Virginia from 1999-2003; Trainee at Philips Research, in Eindhoven, The Netherlands in 1998; Limited Service Employee at Eastman Chemical Co. from 1995-1997; and Chemical Engineer at Eastman Chemical Co. from 1992-1994. I am active in several professional societies, including the American Institute of Chemical Engineers, the American Chemical

Society, the Society for Biomaterials, the Cancer and Bone Society, and the Interdisciplinary Research Society for Bone and Joint Injectable Biomaterials. My research interests include biomaterials design and development, drug and gene delivery, tissue engineering, and *in vitro* models for cancer metastasis to bone.

My experience, education and training and a complete list of my published articles are summarized in my Curriculum Vitae attached to this report as Exhibit A. I have published 83 peer-reviewed articles, including four on the design of scaffolds that degrade in response to secretion of reactive oxygen species and two on oxidation and degradation of polypropylene pelvic mesh. I also have experience in the design of biologic and tissue-engineered grafts for regeneration of cutaneous tissue and bone, having published 24 peer-reviewed papers on biologic tissue grafts. I have co-authored 9 book chapters, given 53 invited presentations, and co-authored 184 abstracts presented at scientific meetings, two of which relate to oxidation of polypropylene in biomedical devices. I am a co-inventor on 11 issued U.S. and European Patents and 20 pending applications.

II. SUMMARY OF OPINIONS

This report is an examination and assessment of the polypropylene mesh utilized in devices manufactured by Ethicon to treat Stress Urinary Incontinence (SUI) and pelvic organ prolapse (POP). All of the opinions presented herein are made to a reasonable degree of scientific certainty and within my field of expertise.

- 1) Polypropylene reacts with molecular oxygen by autoxidation outside the body at elevated temperatures, resulting in chain scission and deterioration in its mechanical properties;
- 2) After implantation in the body, polypropylene reacts with reactive oxygen species secreted by inflammatory cells, resulting in oxidation, chain scission and mesh embrittlement;
- 3) The dynamic environment where the polypropylene mesh is implanted coupled with the foreign body reaction leads to oxidation, chain scission, reduction in molecular weight, embrittlement, degradation, flaking, pitting, and cracking;
- 4) The human body does not stop responding to an implanted mesh, or any frayed particles of mesh released during implantation, unless the product is removed in its entirety;
- 5) The mesh devices examined for this report are intended to last for the lifetime of the patient, but the presence of antioxidants does not permanently protect the PP against degradation, and thus it is not possible to guarantee that it will perform its intended function after implantation;
- 6) The effects of oxidation on the stability of Prolene were known to Ethicon prior to launching its SUI and POP devices, but the company did not consider the risks associated with polypropylene oxidation on the stability of Prolene mesh, to the detriment of patients implanted with the devices;
- 7) Polypropylene mesh is not inert and its properties change after implantation, which can lead to adverse events in an implantee; the use of heavy-weight meshes directly correlates with more exposure of polypropylene to the Foreign Body Reaction and greater changes after implantation, which increases the risk of complications.
- 8) Using autologous fascia lata, allograft, sutures (including polypropylene sutures), or polyvinylidene fluoride (PVDF) mesh does not present with the same chronic complications associated with the material properties of Ethicon's PP mesh. All of these alternative materials, including using a less dense version of its PP mesh, were available when Ethicon's SUI and POP meshes were first commercialized.

III. BACKGROUND

Ethicon sells permanently implantable polypropylene-based meshes intended to treat Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP). All of the products in this litigation use the same Prolene resin to make the polypropylene-based meshes examined in this report.¹ Prolene was developed by Ethicon in the late 1960s for use as a suture material² and is more than 97% polypropylene. Additives are blended with polypropylene to modify its properties, including the antioxidants dilaurelthiodipropionate (DLTDP) and Santonox-R to protect Prolene during high-temperature processing and long-term storage³, and the blue pigment copper phthalocyanate (CPC) to enhance its visibility.⁴ Prolene resin is manufactured as pellets, which are extruded into monofilaments that are subsequently knit into a specific mesh pattern.⁵

Ethicon's SUI devices consist of their instructions for use (IFU), insertion tools, and a high-density mesh (105 g/m²) knit from Prolene monofilaments that are 6 mil (0.006 inches) in diameter.⁶ The Prosima, Prolift, and Gynemesh POP devices all consist of their IFU, insertion tools, and a lower density mesh (45 g/m², known as Gynemesh⁷) knit from Prolene monofilaments that are 3.5 mil (0.0035 inches) in diameter.⁸ The mesh used in the Prolift+M POP device is a hybrid material comprising a blend of absorbable Monocryl (poly(glycolide-co-ε-caprolactone)) and Prolene. After the Monocryl is absorbed, the density of the remaining Prolene mesh is 28 g/m².⁹

¹ ETH.MESH.04941016; ETH.MESH.01310578; ETH.MESH.03987419; ETH.MESH.07876572; ETH.MESH.00019863; ETH.MESH.0181699

² ETH.MESH.02268619

³ ETH.MESH.02268619

⁴ *Id.*

⁵ ETH.MESH. 03987419; ETH.MESH.01310578

⁶ ETH.MESH.04941016

⁷ ETH.MESH.01310578

⁸ ETH.MESH.00074499

⁹ *Id.*

IV. DISCUSSION

1) Polypropylene reacts with molecular oxygen outside the body by the process of autoxidation

Polypropylene (PP) is a plastic that is formed by a chemical reaction that joins the monomer propylene (which is composed of three carbon atoms and six hydrogen atoms) into a long repeating chain in a process called polymerization.¹⁰ All forms of PP are susceptible to oxidation at the tertiary hydrogen-carbon bond.¹¹

Oxidative attack at the tertiary hydrogen bond is the rate-controlling step in degradation process and results in the PP molecular chain being broken, a process known as chain scission, with the consequent loss in molecular weight. The mechanism of PP autoxidation is shown in Figure 1.¹² The process is autocatalytic, resulting in generation of more PP radicals (PP•) as the reaction progress. Thus, the reaction continues until no more PP can be broken down. The mechanism of PP autoxidation has been investigated extensively since the 1960s and was well known at the time that Ethicon was designing the mesh used in SUI and POP products. As shown in Figure 1, the products of autoxidation include shorter PP chains with carbonyl (C=O) and hydroperoxide (COOH) groups covalently bound to the PP. The presence of these groups can be detected by surface techniques such as FTIR and x-ray photoelectron spectroscopy (XPS) as evidence of

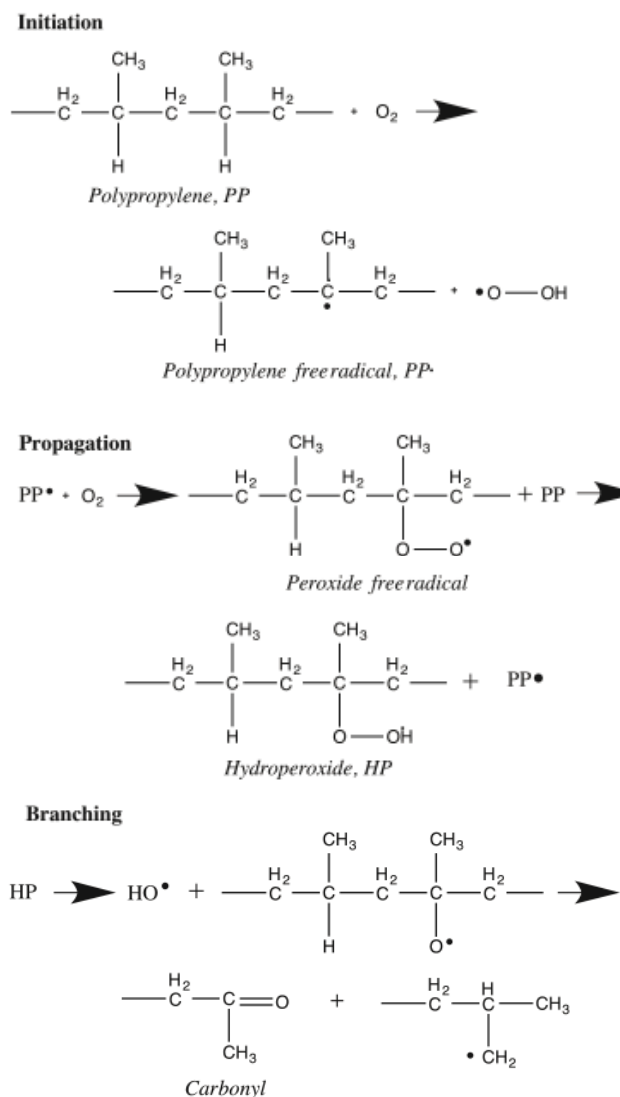


Figure 1. Mechanism of PP autoxidation. Initiation, propagation, and branching reactions lead to chain scission (loss of molecular weight). Products from autoxidation include hydroperoxide and carbonyl groups, which can be detected by analytical methods such as FTIR.

¹⁰ EA Campo. Industrial Polymers. Hanser 2008, p. 74.

¹¹ HH Kausch. The effect of Degradation and Stabilization on the Mechanical Properties of Polymers Using Polypropylene Blends as the Main Example. *Macromol. Symp.* 225:165-178, 2005.

¹² Reference for Figure 1: C Maier, T Calafut. Polypropylene: The Definitive User's Guide and Databook. Norwich, NY: Plastics Design Library, 1998.

oxidation.¹³

As shown in Figure 2, heat and UV radiation accelerate oxidation of PP.¹⁴ Absorption of oxygen is diffusion-controlled, and the amorphous regions of the semi-crystalline PP are the most accessible to diffusion of O₂. The amorphous phase of PP comprises non-crystallizable segments of the PP chains as well as tie molecules that connect two neighboring crystalline domains. Since the toughness of PP depends on the number of tie molecules, cutting of the tie molecules during autoxidation is the primary factor contributing to embrittlement. The key features of oxidation of PP, in terms of the amount of molecular weight loss that is critical for embrittlement to occur are summarized in Figure 3.¹⁵ An important finding from this study is that embrittlement occurs much earlier (~150 hours) than the induction time (~250 hours) determined by the concentration of carbonyl groups and hydroxyl groups associated with the hydroperoxide (COOH) under these conditions. Thus, the induction time overestimates the useful life of PP with respect to its mechanical properties.

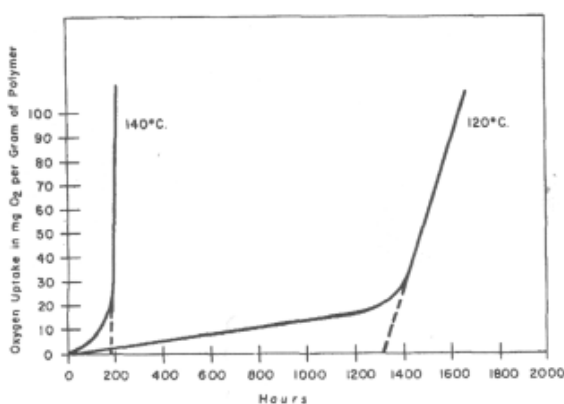


Figure 2. Autoxidation of PP is accelerated at elevated temperatures. Oxygen absorption of stabilized PP increases with time and temperature in 100% O₂. The induction time is determined by extrapolating the autocatalytic constant rate portion of the curve (steeper slope) to the x-axis (dashed line). Reproduced from Oswald and Turi 1965.

The storage stability of unstabilized PP at ambient conditions has also been studied (Figure 4). When PP films were stored at room temperature and atmospheric O₂ concentration, the molecular weight (as measured by intrinsic viscosity) of PP dramatically decreased at 500 days (1.4 years).¹⁶ Thus, while oxidation is accelerated at elevated temperatures and oxygen concentrations (Figure 2), even at ambient temperature and atmospheric oxygen concentration there is chain scission and molecular weight loss.

2) After implantation in the body, polypropylene reacts with reactive oxygen species secreted by inflammatory cells, resulting in oxidation, chain scission and mesh embrittlement;

Liebert et al.¹⁷ (1976) reported the oxidation of unstabilized PP filaments in vivo in a subcutaneous implantation model in hamsters. An induction time of 108 days was determined based on FTIR measurements of hydroxyl (which includes the hydroperoxide

¹³ B Fayolle, L Audouin, J Verdu. Oxidation-induced embrittlement in polypropylene – a tensile testing study. *Polym Degrad Stability* 70:333-40, 2000.

¹⁴ HJ Oswald, E. Turi. The Deterioration of Polypropylene by Oxidative Degradation. *Polymer Engineering and Science*, 1965.

¹⁵ B Fayolle, L Audouin, J Verdu. Oxidation-induced embrittlement in polypropylene – a tensile testing study. *Polym Degrad Stability* 70:333-40, 2000.

¹⁶ HJ Oswald and E. Turi. The Deterioration of Polypropylene by Oxidative Degradation. *Polymer Engineering and Science*, 1965.

¹⁷ TC Liebert, RP Chartoff, SL Cosgrove, RS McCuskey. Subcutaneous implants of polypropylene filaments. *Journal Biomedical Materials Research* 10:939-51, 1976.

COOH) and carbonyl groups. FTIR measurements of hydroxyl and carbonyl groups showed behavior similar to that observed by Fayolle (Figure 3), consistent with the oxidation mechanism. However, Liebert estimated that the induction time for oxidation under *in vivo* conditions (37°C in 3.3% O₂) is approximately 20 years, which is dramatically higher than the measured value of 108 days. The authors suggested that enzymes or other chemicals secreted by cells accelerate the oxidation reaction. Recent papers have shown that this shorter induction time can be explained by the secretion of reactive oxygen species (ROS) by inflammatory cells near the PP fibers that oxidize and degrade the PP fibers *in vivo*.

Upon implantation, the body recognizes PP mesh as a foreign body, which elicits an inflammatory response known as the foreign body reaction.¹⁸ In the early stages, mononuclear cells migrate to the surface of the PP fibers, where they can adhere and participate in the events of the foreign body reaction (Figure 5). Adherent macrophages on the surface of the implanted biomaterial fuse to form foreign body giant cells (FBGCs). Adhesion of macrophages and FBGCs at the biomaterial surface results in an isolated microenvironment between the surface of the biomaterial and the plasma membrane of the cell.¹⁹ In a process known as frustrated phagocytosis, macrophages and FBGCs secrete reactive oxygen species (ROS), acids, and enzymes into this microenvironment. Consequently, the surface of the biomaterial is exposed to high concentrations of ROS, and the chemical composition of the biomaterial will determine its susceptibility to oxidative degradation. As an example, the polyether soft segment of poly(ether urethane)s is known to undergo oxidative degradation. The morphological progression of the foreign body reaction on a poly(ether urethane) surface is shown in Figure 6.²⁰

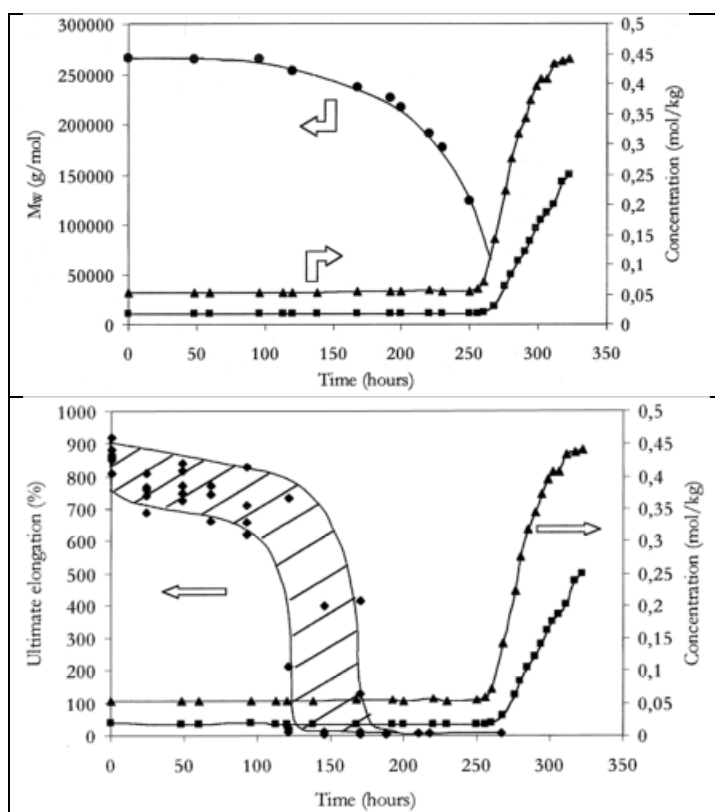


Figure 3. Degradation of unstabilized PP. (A) Molecular weight decreases with time when exposed to oxygen at elevated temperatures (Fayolle et al. 2000). On the right y-axis, the concentration of hydroxyl (triangles) and carbonyl (squares) groups are shown. (B) Evolution of ultimate elongation (diamonds) and hydroxyl (triangles) and carbonyl (squares) groups during exposure to oxygen at elevated temperatures (Fayolle et al. 2000).

¹⁸ JM Anderson, A Rodriguez, DT Chang. Foreign Body Reaction to Biomaterials. *Semin Immunol.* 20(2): 86–100, 2008.

¹⁹ *Id.*

²⁰ *Id.*

While initial studies identifying adherent macrophages and FBGCs as sources of ROS focused on poly(ether urethane)s, these cell populations have also been reported to infiltrate PP mesh.²¹ In a recent study characterizing the foreign body reaction of PP implants in a rat abdominal wall model, macrophages and foreign body giant cells were observed both in the tissue surrounding the implant and also the implant itself.²²

Thus, within one week after implantation PP mesh was colonized by macrophages and FBGCs. Furthermore, PP mesh samples showed more inflammatory cells than PP sutures. The hernia literature also provides evidence that the foreign body reaction alters PP *in vivo*. In a study evaluating non-degradable meshes explanted from 17 patients that had surgery for repair of abdominal wall defects, a foreign body reaction characterized by granulation tissue and inflammatory cells 3 – 24 months post-implantation was seen.²³ The authors

observed that inflammation near synthetic materials implanted in the abdominal wall persists for years. They further noted that this persistent foreign body reaction can lead to long-term complications, and that further studies are required to evaluate the long-term response of the host tissue to the implanted synthetic graft. Costello et al. also examined explanted PP hernia mesh and noted that the observed degradation of PP fibers was consistent with the oxidation of PP mediated by phagocytic cells during the foreign body reaction.²⁴

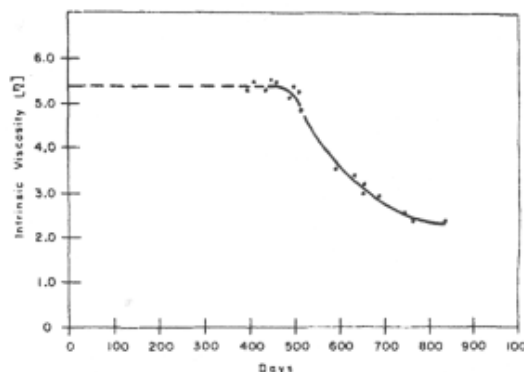


Figure 4. Stability of unstabilized PP at room temperature. Significant molecular weight loss occurs at 500 days. Reproduced from Oswald and Turi 1965.

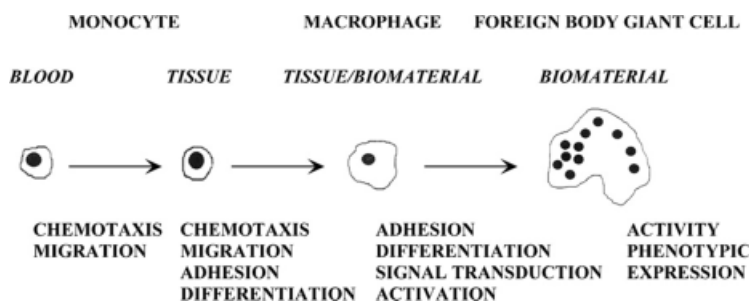


Figure 5. *In vivo* transition from blood-borne monocyte to biomaterial adherent monocyte/macrophage to foreign body giant cell at the tissue/biomaterial interface. There is ongoing research to elucidate the biological mechanisms that are considered to play important roles in the transition to foreign body giant cell development. From Anderson et al. Seminars in Immunology 2008.

²¹ C Mary, Y Marois, MW King, G Laroche, Y Douville, L Martin, R Guidoin. Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and polypropylene Sutures Used in Vascular Surgery. *ASAIO Journal* 44:199-206, 1998; VV Iakovlev, ET Carey, J Steege. Pathology of Explanted Transvaginal Meshes. *Int. J. Medical, Health, Pharmaceutical and Biomedical Eng.* 8(9):510-513, 2014

²² ML Konstantinovic, E Pille, M Malinowska, E Verbeken, D De Ridder, J Deprest. Tensile strength and host response towards different polypropylene implant materials used for augmentation of fascial repair in a rat model. *Int Urogynecol J* 18:619-26, 2007.

²³ U Klinge, B Klosterhalfen, M. Müller, V Schumpelick. Foreign Body Reaction to Meshes Used for the Repair of Abdominal Wall Hernias. *Eur J Surg* 165: 665–673, 1999.

²⁴ CR Costello, SL Bachman, BJ Ramshaw, SA Grant. Materials Characterization of Explanted Polypropylene Hernia Meshes. *J. Biomed. Mater. Res. Part B Appl. Biomater* 83:44-49, 2007; CR Costello, SL Bachman, SA Grant, DS Cleveland, TS Loy, BJ Ramshaw. Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants from a Single Patient. *Surg. Innov.* 14:168-76, 2007.

Three key studies published in 2015 that characterize the host inflammatory response to implanted PP provide further evidence that PP mesh undergoes oxidative degradation *in vivo*. Gynemesh PS and UltraPro, which are Prolene meshes used in Ethicon's POP products, were implanted in rhesus macaques by sacrocolpopexy after an abdominal hysterectomy.²⁵ After 12 weeks implantation time, the vagina-mesh tissue complexes were harvested and processed for histological and immunohistochemical analysis. Explanted Gynemesh PS and UltraPro meshes showed evidence of a foreign body reaction characterized by a dense mononuclear cell infiltrate near the surface of the mesh fibers. Mononuclear cells staining positive for the pan-macrophage marker CD68 were the cell type present at the highest density adjacent to the mesh fibers. The inflammatory response to all implanted PP meshes was characterized primarily by activated, pro-inflammatory M1 macrophages (an example of macrophages on Elasthane 80A are shown in Figure 7, Top Left).²⁶ The ratio of regenerative M2 macrophages to M1 macrophages was higher for the lower density UltraPro mesh compared to the

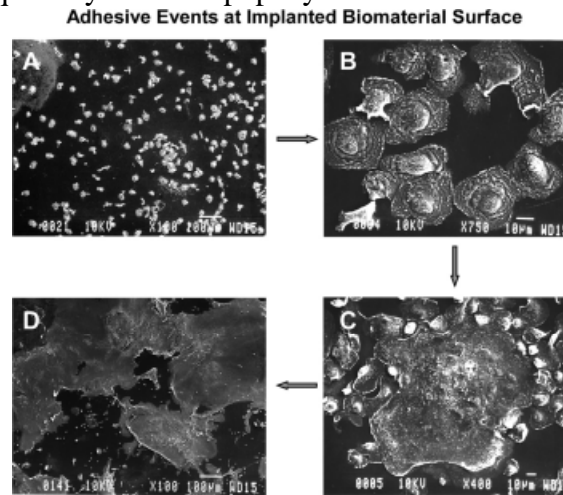


Figure 6. Scanning electron microscopy images of an Elasthane 80A Polyurethane surface from an *in vivo* cage study showing the morphological progression of the foreign body reaction. The sequence of events at the Polyurethane surface includes (A) monocyte adhesion (0 days), (B) monocyte-to-macrophage development (3 days), (C) ongoing macrophage-macrophage fusion (7 days), and (D) foreign body giant cells (14 days). From JM Anderson, A Rodriguez, DT Chang. Foreign Body Reaction to Biomaterials. *Semin Immunol.* 20(2): 86–100, 2008.

²⁵ BN Brown, D Mani, AL Nolfi, R Liang, S Abramowitch, PA Moalli. Characterization of the host inflammatory response following implantation of prolapse mesh in rhesus macaque. *Am J Obstet Gynecol.* 213(5):668.e1-668.e10, 2015.

²⁶ JM Anderson, A Rodriguez, DT Chang. Foreign Body Reaction to Biomaterials. *Semin Immunol.* 20(2): 86–100, 2008.

higher density Gynemesh PS. This finding is consistent with the mesh burden concept that the magnitude of the foreign body reaction increases with the amount of mesh in contact with host tissue. Thus, the work by Moalli et al. establishes that the foreign body reaction to implanted PP mesh is dominated by pro-inflammatory M1 macrophages. In a study I co-authored with Dr. Vladimir Iakovlev in 2015, we examined 164 explanted PP pelvic meshes by microscopy.²⁷ Examination of histological sections revealed the presence of inflammatory cells near the surface of PP fibers, and staining for the oxidative enzyme myeloperoxidase expressed by adherent inflammatory cells was positive on the surface of the

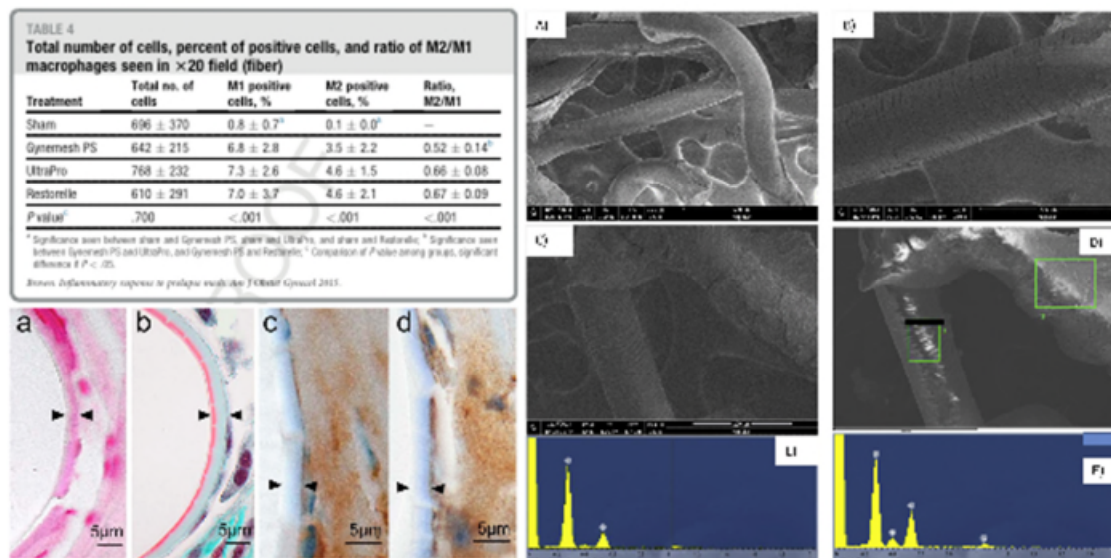


Figure 7. Oxidative degradation of PP mesh *in vivo*. Top Left: Table listing the total number of cells, percent of positive cells, and ratio of M2/M1 macrophages seen in $\times 20$ field (fiber) (Moalli et al., Characterization of the host inflammatory response following implantation of prolapse mesh in rhesus macaque.) Bottom Left: Additional stains of PP mesh, all images taken with 100x oil immersion objective and cropped to a different magnification, polypropylene degradation layer is pointed between arrowheads: (a) Von Kossa stain is negative for calcium in the brittle “bark” (would stain calcium black), (b) trichrome stain shows that the deeper parts of the “bark” have smaller staining porosity (red) than those close to the surface (green) which correlates with TEM findings [Figure 6(b)], (c) immunohistochemical stain for immunoglobulin G (IgG, stained brown). IgG is present in almost all human tissues and fluids. It is deposited on the surface of degraded polypropylene but is not mixed within it. (d) Immunostain for the oxidizing enzyme of inflammatory cells myeloperoxidase (stains brown). (VV Iakovlev. *In vivo* degradation of polypropylene: microscopic analysis of meshes explanted from 130 patients.) Right: A) SEM of explanted Pinnacle Mesh fibers [XP-7]. B) SEM of explanted Pinnacle Mesh fibers [XP-7]. C) SEM of explanted Pinnacle Mesh fibers [XP-7]. D) SEM image with regions selected for EDS. E) EDS Spectra from region 1 in D. F) EDS Spectra from region 2 in D. (A Imel, T Malmgren, M Dadmun, S. Gido, J Mays. *In vivo* oxidative degradation of polypropylene pelvic mesh, *Biomaterials*, 2015.).

degraded layer of the PP fibers (Figure 7, Bottom Left). Another study published in 2015 confirmed that the foreign body reaction to implanted PP mesh results in oxidative degradation of the mesh.²⁸ PP pelvic meshes explanted from 11 patients were characterized by FTIR, GPC, SEM with energy-dispersive x-ray spectroscopy (EDS), TEM, and TGA and compared to meshes that had not been implanted. FTIR spectra of explanted PP mesh showed broad peaks centered at 3400 cm^{-1} , which correspond to hydroxyl and peroxide groups, and at $1700 - 1750\text{ cm}^{-1}$, which correspond to carbonyl

²⁷ VV Iakovlev, SA Guelcher, R Bendavid. *In vivo* degradation of polypropylene: microscopic analysis of meshes explanted from 130 patients. *J Appl Biomed Mater Res B: Appl Biomater* 105(2):237-248, 2017.

²⁸ A Imel, T Malmgren, M Dadmun, S. Gido, J Mays. *In vivo* oxidative degradation of polypropylene pelvic mesh. *Biomaterials* 73:131-141, 2015.

groups associated with ketones, aldehydes, and carboxylic acids. Importantly, this study demonstrated that oxidized PP, which does not contain nitrogen, and biological material, which does contain nitrogen, could be distinguished by a combination of EDS and SEM. Regions of PP fibers with transverse cracks that were free of biological material were found to contain oxidized PP (Figure 7 Right). Furthermore, clean PP fibers that showed no evidence of transverse cracking revealed evidence of PP oxidation.

Two recent studies by the Moalli group at the University of Pittsburgh have reported the effects of PP mesh on host tissue and the inflammatory response. When PP mesh was implanted in the vaginal wall of rhesus macaques, mesh stiffness and density were negatively correlated with muscle outcomes, including myofiber function, contraction, and innervation.²⁹ Moalli et al. also examined the inflammatory response in fifteen SUI and twelve POP meshes explanted from 27 women, including two TVT meshes.³⁰ Histological analysis revealed evidence of macrophages, which were predominantly of the M1 pro-inflammatory phenotype, surrounding PP mesh fibers. Matrix metalloproteinase-9 (MMP-9) and MMP-2, which are associated with chronic inflammation, were significantly upregulated in mesh-vagina explants compared to vaginal tissue without mesh.³¹ Mesh explants that were removed due to exposure exhibited significantly higher pro-MMP-9 than those removed due to pain. These findings show that mesh exposure correlates with expression of factors associated with inflammation.

In a manuscript recently accepted for publication, I have shown that PP mesh oxidizes and degrades *in vitro*.³² TVT, Advantage (Boston Scientific), and Lynx (Boston Scientific) mesh specimens were incubated in oxidative medium that mimics the reactive oxygen species (ROS) secreted by adherent inflammatory cells.³³ PP oxidized and degraded *in vitro* in the absence of proteins, as evidenced by the appearance of oxygen (measured by FTIR) and pitting, peeling, and flaking on the surface (measured by SEM). In a patient explant, manual dissection of mesh not fixed in formalin successfully removed protein

²⁹ Z Jallah, R Liang, A Feola, W Barone, S Palcsey, SD Abramowitch, N Yoshimura, and P Moalli. The impact of prolapse mesh on vaginal smooth muscle structure and function. *BJOG* 23:1076–1085, 2016.

³⁰ AL Nolfi, BN Brown, R Liang, SL Palcsey, MJ Bonidie, SD Abramowitch, PA Moalli. Host response to synthetic mesh in women with mesh complications. *Am J Obstet Gynecol* 215:206.e1-8, 2016.

³¹ *Id.*

³² AD Talley, BR Rogers, V Iakovlev, RF Dunn, and SA Guelcher. Oxidation and degradation of polypropylene transvaginal mesh. *Journal of Biomaterials Science: Polym Ed* 28(5):444-458, 2017.

³³ QH Zhao, AK McNally, KR Rubin, M Renier, Y Wu, V Rose-Caprara, JM Anderson, A Hiltner, P Urbanski, K Stokes. Human plasma macroglobulin promotes in vitro oxidative stress cracking of Pellethane 2363-80A: In vivo and in vitro correlations. *J Biomed Mater Res* 27: 379-389, 1993. AE Hafeman, KJ Zienkiewicz, AL Zachman, HJ Sung, LB Nanney, JM Davidson, SA Guelcher. Characterization of degradation mechanisms of biodegradable lysine-derived aliphatic polyurethanes. *Biomaterials* 32(2):419-29, 2011. JL Martin, MK Gupta, JM Page, F Yu, JM Davidson, SA Guelcher, CL Duvall. Synthesis of a Porous, Biocompatible Tissue Engineering Scaffold Selectively Degraded by Cell-Generated Reactive Oxygen Species. *Biomaterials* 35(12):3766-76, 2014. MAP McEnery, S Lu, MK Gupta, KJ Zienkiewicz, JC Wenke, K Kalpakci, D Shimko, CL Duvall, SA Guelcher. Resorbable Poly(thioketal urethane)/Ceramic Composite Bone Cements with Bone-Like Strength. *RSC Advances* 6:109414 - 109424, 2016. JR Martin, CE Nelson, MK Gupta, F Yu, KM Hocking, JM Davidson, SA Guelcher, CL Duvall. Local delivery of PHD2 siRNA from ROS-degradable scaffolds to promote diabetic wound healing. *Adv Healthc Mater* 5(21):2751-2757, 2016.

from the surface, revealing an underlying layer of oxidized PP. XPS analysis of these mechanically scraped fibers showed negligible nitrogen but a significant amount of oxygen on the surface. Furthermore, oxygen was present in C=O and COOH bonds as predicted by the oxidation mechanism. These findings cannot be explained by the notion that the surface is coated by a crosslinked protein-formaldehyde complex as proposed by Thames et al.³⁴, since the samples were never fixed in formalin.

Thames et al. recently published a study reporting that the surface of PP is coated by a crosslinked protein-formaldehyde complex.³⁵ However, both internal Ethicon studies from the 1980s as well as recently published papers have reported that the surface cracked layer is a complex composite of oxidized PP and adsorbed protein. Thus, while the Thames et al. cleaning protocol may be adequate for removing all of the adsorbed protein, it is not sufficient to characterize the composition and structure of the surface cracked layer. Alternative cleaning procedures that remove only the proteins in the “layer structure” should be used to avoid removing the “protein trapped by microcracks”³⁶ (Figure 8), which enables a more rigorous analysis of the surface cracked layer. Procedures previously used to clean PP sutures, hernia mesh, and pelvic mesh utilized sodium hypochlorite (bleach) solution, enzymatic solutions, or Soluene³⁷ to selectively remove proteins and tissue from the “layer structure” (Figure 1). Recommended protocols for analyzing explanted biomedical devices are described in ISO 12891. While no method is listed for cleaning PP explants, the standard recommends cleaning with sodium hypochlorite (bleach) solution for the closely related polyolefin, ultra-high molecular weight polyethylene.³⁸ In contrast, sonication is used to clean metals and jewels, remove dental plaque, and pulverize renal calculi.³⁹ Consequently, sonication for long periods of time (as reported by Thames et al.⁴⁰) can remove all detachable materials non-specifically, and is therefore not suitable for investigating the composition and structure of the surface

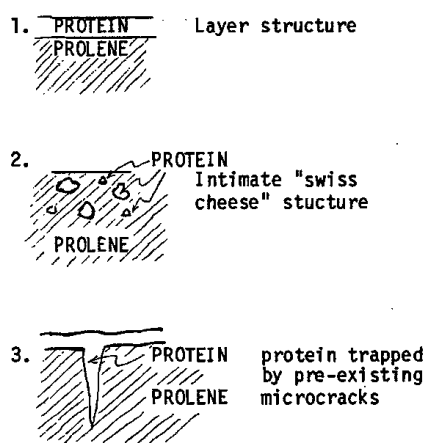


Figure 8. Three protein deposition mechanisms proposed by Dr. Peter Moy. ETH.MESH.15958445

³⁴ SF Thames, JB White, KL Ong. The myth: in vivo degradation of polypropylene-based meshes. *Int Urogynecol J* 28(2):285-297, 2017. M Thompson, SA Guelcher, R Bendavid, V Iakovlev, DR Ostergard. In vivo polypropylene mesh degradation is hardly a myth. *Int Urogynecol J* 28(2):333-335, 2017. SF Thames, JB White, KL Ong KL. Reply to "In vivo polypropylene mesh degradation is hardly a myth". *Int Urogynecol J* 28(2):337-338, 2017.

³⁵ SF Thames, JB White, KL Ong. The myth: in vivo degradation of polypropylene-based meshes. *Int Urogynecol J* 28(2):285-297, 2017. M Thompson, SA Guelcher, R Bendavid, V Iakovlev, DR Ostergard. In vivo polypropylene mesh degradation is hardly a myth. *Int Urogynecol J* 28(2):333-335, 2017. SF Thames, JB White, KL Ong KL. Reply to "In vivo polypropylene mesh degradation is hardly a myth". *Int Urogynecol J* 28(2):337-338, 2017.

³⁶ ETH.MESH.15958445.

³⁷ <http://www.perkinelmer.com/product/soluene-350-0-5-l-6003038>

³⁸ A Imel, T Malmgren, M Dadmun, S. Gido, J Mays. In vivo oxidative degradation of polypropylene pelvic mesh. *Biomaterials* 73:131-141, 2015

³⁹ M Thompson, SA Guelcher, R Bendavid, V Iakovlev, DR Ostergard. In vivo polypropylene mesh degradation is hardly a myth. *Int Urogynecol J*. 28(2):333-335, 2017.

⁴⁰ SF Thames, JB White, KL Ong. The myth: in vivo degradation of polypropylene-based meshes. *Int Urogynecol J*. 28(2):285-297, 2017.

cracked layer. Dan Burkley, an Ethicon employee, noted the appearance of the surface scrapings from explanted Prolene sutures as resembling a “waxy snow”⁴¹, which implies a friable material and is in agreement with a recent study reporting that the surface of explanted PP mesh fibers is cracked and porous.⁴² Step #8 of the Thames et al. cleaning protocol comprised immersion in bleach solution in an ultrasonic bath for 1.5 h. This step is the second bleach treatment, after which the peaks ranging from 1500 – 1750 cm⁻¹, which are associated with carbonyl groups in proteins and oxidized PP, disappeared from the FTIR spectrum. This observation is consistent with the notion that sonication non-selectively debrides the surface of the PP fiber and removes all adherent material, including adsorbed proteins and oxidized PP. Thames et al. neglected to note that oxidized PP exhibits absorbance frequencies (1600 – 1699 cm⁻¹ for carbonyl groups and 3409 cm⁻¹ for hydroxyl groups) over ranges similar to those of the protein frequencies reported in their study, as described in internal Ethicon documents⁴³ and published studies.⁴⁴ Thus, Thames et al. cannot exclude the possibility that the cracked surface layer was composed of a complex mixture of oxidized PP and protein. Clave et al. noted that “FTIR absorption bands between 1,615 and 1,650 cm⁻¹ could be attributed either to carboxylate carbonyl or to residual products of biological origin. Therefore, these results cannot confirm the formation of carboxyl groups in vivo.”⁴⁵ While Clave et al. did not speculate further on the composition of the cracked layer, it is important to note that their observations did not exclude the possibility of protein or oxidized PP. However, Thames et al. assumed that the cracked surface layer was protein on the basis of FTIR absorption frequencies associated with proteins (amide N-H stretching in the 3,300 cm⁻¹ region and amide I carbonyl stretching in the region of 1,600–1,690 cm⁻¹) without noting the existence of overlapping peaks in the FTIR spectra of oxidized PP (1600 – 1699 cm⁻¹ for carbonyl groups and 3409 cm⁻¹ for hydroxyl groups).

More rigorous methods than those used by Thames et al. are required to correctly identify the composition of the cracked surface layer. Published studies as well as internal Ethicon studies have determined that the cracked surface layer contains oxidized PP. Mr. Burkley analyzed the surface scrapings removed from Prolene sutures explanted from patients using melting point analysis and FTIR, which led him to conclude that the surface contained oxidized PP and protein.⁴⁶ His experiments using Soluene to selectively extract tissue from the surface led him to conclude that Soluene could remove the protein adhering to the surface of the fibers but not protein that had penetrated into the pores.⁴⁷ Iakovlev et al. used microscopic analysis of axial cross sections of explanted PP mesh fibers to show that surface cracks were predominantly oxidized PP.⁴⁸ Imel et al. used EDS⁴⁹ and Talley et al. used XPS⁵⁰ to identify regions of PP fibers from explanted mesh

⁴¹ ETH.MESH.12831391

⁴² VV Iakovlev, SA Guelcher, R Bendavid. *In vivo* degradation of polypropylene: microscopic analysis of meshes explanted from 130 patients. *J Appl Biomed Mater Res B: Appl Biomater* 105(2):237-248, 2017.

⁴³ ETH.MESH.12831391; ETH.MESH.15958452; Memo to Dr. AJ Melveger from Dr. P Moy, Prolene Microcracking, November 5, 1984.

⁴⁴ AD Talley, BR Rogers, V Iakovlev, RF Dunn, and SA Guelcher. Oxidation and degradation of polypropylene transvaginal mesh. *J Biomater Sci Polym Ed* 28(5):444-458, 2017.

⁴⁵ A Clave, H Yahi, J-C Hammou, S Montanari, P Gounon, H Clave. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. *Int Urogynecol J* 21:261-270, 2010.

⁴⁶ ETH.MESH.12831391; ETH.MESH.15958452

⁴⁷ ETH.MESH.15958336

⁴⁸ VV Iakovlev, SA Guelcher, R Bendavid. *In vivo* degradation of polypropylene: microscopic analysis of meshes explanted from 130 patients. *J Biomed Mater Res: Part B Appl Biomater* 105(2):237-248, 2017.

⁴⁹ A Imel, T Malmgren, M Dadmun, S. Gido, J Mays. *In vivo* oxidative degradation of polypropylene pelvic mesh. *Biomaterials* 73:131-141, 2015.

that showed evidence of oxygen on the surface but not nitrogen, which can be explained by oxidation but not protein adsorption. Thames et al. could have used any of these methods to independently characterize the composition of the cracked surface layer rather than simply assume it was protein on the basis of FTIR measurements. Without a more rigorous analysis of the cracked surface layer, it cannot be concluded that it did not include oxidized PP.

3) The dynamic environment where the Prolene mesh is implanted coupled with the foreign body reaction leads to oxidation, chain scission, reduction in molecular weight, embrittlement, degradation, flaking, pitting, and cracking;

In an early study, Prolene sutures implanted for 1 – 2 years in a canine thoracoabdominal bypass model showed evidence of transverse cracks and peeling (Mary 1998).⁵¹ Several more recent studies have reported degradation of explanted PP pelvic mesh. In the first study characterizing explanted pelvic mesh, Clavé et al. reported that 42% of the explants showed evidence of chronic inflammation, characterized by an infiltrate of mononuclear cells and FGBCs. SEM analysis revealed that the implants were degraded, and that degradation was observed in meshes that had been implanted for at least 3 months.⁵²

In 1985, Ethicon implanted 24 beagles with PROLENE, PVDF, Ethilon, and Novafil sutures subcutaneously in a 10-year study. The study was ended at 7 years due to the unexpected death of one of the dogs at 6 years and 10.5 months. At 7 years, Dr. Lindemann noted that “degradation in Prolene is still increasing”⁵³ and that three of the seven explanted Prolene sutures showed evidence of surface cracking.⁵⁴ Mr. Burkley noted that IR spectra for cracked Prolene specimens “showed possible evidence of slight oxidation (a broadened weak absorbance at about 1650 cm⁻¹).”⁵⁵ Differences in the crosshead (XH) speed of the testing device can explain the increased elongation at break reported for the 7-year explants, as summarized in Table 1 below:

Table 1. Crosshead speed used to measure tensile properties of the Prolene sutures explanted from dogs.

⁵⁰ AD Talley, BR Rogers, V Iakovlev, RF Dunn, and SA Guelcher. Oxidation and degradation of polypropylene transvaginal mesh. *J Biomater Sci Polym Ed* 28(5):444-458, 2017.

⁵¹ C Mary, Y Marois, MW King, G Laroche, Y Douville, L Martin, R Guidoin. Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery. *ASAIO Journal* 44:199-206, 1998.

⁵² A Clave, H Yahi, J-C Hammou, S Montanari, P Gounon, H Clave. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. *Int Urogynecol J* 21:261-270, 2010.

⁵³ ETH.MESH.09888187.

⁵⁴ ETH.MESH.09888187.

⁵⁵ ETH.MESH.09888187.

Reference	Date	Action
ETH.MESH.11336184	5/30/85	XH speed was specified as 5 in / min for all products in the protocol
ETH.MESH.11336184	8/21/87	XH speed was changed to 10 in / min for all products
ETH.MESH.11336071	8/18/88	XH speed was reported as 1 in / min for the 1 yr and 2 yr Prolene explants and 5 in / min for all other 1- and 2-yr explants
ETH.MESH.11336071	9/20/88	XH speed was reported as 10 in /min for all products in the 2-yr interim report
ETH.MESH.05453719	10/19/92	XH speed was reported as 1 in / min for the 7-yr Prolene explants and 5 in / min for all other 7-yr explants

The crosshead speed is a measure of the rate at which the test specimen is strained. As the crosshead speed decreases, the tensile modulus of the polymer being tested decreases while the elongation rate increases.⁵⁶ Thus, the crosshead speed is an important experimental parameter, but it is not clear what the crosshead speed was at each of the experimental conditions. As shown in Table 1, the crosshead speed was initially specified as 5 in / min in the original animal protocol. Two years later, the crosshead speed was changed to 10 in / min for all products. However, other documents state that crosshead speeds different from those specified in the protocol were used for 1-, 2-, and 7-year explants, and that these speeds were different for Prolene sutures compared to the other sutures.⁵⁷ Therefore, I find the tensile testing of sutures from the dog study to be unreliable due to these discrepancies in the crosshead speeds used for the testing.

In the study that I co-authored with Dr. Iakovlev⁵⁸, a layer of degraded PP was observed by optimal microscopy near the surface of the fibers in the explanted mesh (Figure 7). Micro-cracks were present in the degraded PP layer. Degradation and cracking of the polypropylene fibers was observed as early as 18 months for a cohort of 23 explanted PP SUI devices.

Mays et al. also observed degradation of fiber in explanted PP mesh using SEM. Using a combination of SEM and EDS, the authors were able to distinguish between fibers that were clean and those that were coated with biological material. Explanted fibers were observed that showed evidence of severe transverse cracks (Figure 7), which was accompanied by oxidative degradation of the fibers. The authors identified the mechanism of PP degradation as comprising the following steps: infiltration of inflammatory cells that secrete ROS in close proximity to the PP mesh fibers, oxidative degradation of the PP fibers characterized by the appearance of hydroxyl and carbonyl groups in the FTIR spectra, a reduction in molecular weight, embrittlement, cracking, and fragmentation of the PP fibers.

4) PP mesh is known to fray under tension and release particles while being handled

⁵⁶ EA Campo. *Selection of Polymeric Material: How to Select Design Properties from Different Standards*. A volume in *Plastics Design Library*, William Andrew Applied Science Publishers, Norwich, NY 2008.

⁵⁷ ETH.MESH.11336071; ETH.MESH.05453719.

⁵⁸ VV Iakovlev, SA Guelcher, R Bendavid. In vivo degradation of polypropylene: microscopic analysis of meshes explanted from 130 patients. *Journal of Applied Biomedical Materials Research B: Applied Biomaterials* 105(2):237-248, 2017.

and implanted. The human body does not stop responding to these particles or to the PP mesh unless the product is removed in its entirety;

As an example of how oxidation of an implanted biomaterial affects its performance, poly(ether urethane)s (PEUs) were used as pacemaker lead insulation due to their improved mechanical properties as compared to silicone rubber. While PEU elastomers were believed to be biocompatible for many years, they are now known to undergo environmental stress cracking due to oxidative degradation of the polyether component and subsequent loss in molecular weight.⁵⁹ Adherent macrophages and FBCGs were shown to be responsible for environmental stress cracking. Thus oxidative degradation and environmental stress cracking comprise a vicious cycle in which oxidative degradation drives the embrittlement of the polymer surface and its subsequent cracking, which in turn exposes new surfaces of the material to oxidative degradation. Another study has shown that ROS actively degrades lysine-derived poly(ester urethane)s *in vivo* by an oxidative mechanism.⁶⁰ Thus, oxidative degradation of biomaterials *in vivo* in response to ROS secreted by inflammatory cells is well known.

Since the foreign body reaction is present at the biomaterial surface for the lifetime of the implant, the oxidative process is ongoing as long as the implant is present.⁶¹ Considering the ongoing foreign body reaction as well as the known susceptibility of PP to oxidation, the mechanical and physical properties of Ethicon's PP mesh will change after it is implanted.

In addition, the properties of Ethicon's PP mesh have been shown to change under tension and while the mesh is being handled.⁶² The medical literature and Ethicon's internal studies have reported that particles are lost or shed from the TVT mesh while it is in the box and while it is being implanted.⁶³ The foreign body reaction to shed particles will be similar to that for the TVT mesh. The body will not stop responding to any particles that are shed inside the body during implantation until those particles are removed in their entirety.

- 5) Ethicon's pelvic meshes are intended to last for the lifetime of the patient, but the presence of antioxidants does not permanently protect the PP against degradation, and thus it is not possible to guarantee that these meshes will perform their intended function after implantation.**

Although PP can never be considered inert, it is stabilized against oxidation by adding antioxidants to the molten polymer, which are intended to act as scavengers that will react

⁵⁹ *Id.*

⁶⁰ AE Hafeman, KJ Zienkiewicz, AL Zachman, HJ Sung, LB Nanney, JM Davidson, SA Guelcher. Characterization of degradation mechanisms of biodegradable lysine-derived aliphatic polyurethanes. *Biomaterials* 32(2):419-29, 2011; J Martin, MK Gupta, JM Page, F Yu, JM Davidson, SA Guelcher, CL Duvall. Synthesis of a Porous, Biocompatible Tissue Engineering Scaffold Selectively Degraded by Cell-Generated Reactive Oxygen Species. *Biomaterials* 35(12):3766-76, 2014.

⁶¹ JM Anderson, A Rodriguez, DT Chang. Foreign Body Reaction to Biomaterials. *Semin Immunol* 20(2): 86-100, 2008.

⁶² ETH.MESH.01813975; ETH.MESH.01317515; ETH.MESH.03905472; ETH.MESH.00541379; ETH.MESH.00863391.

⁶³ *Id.*

with oxidative species.⁶⁴ The enduring nature of the foreign body reaction emphasizes the need for antioxidants to be added to biomaterials such that the time to oxidation, degradation, and embrittlement is extended.⁶⁵ PP in its pure (i.e., unstabilized) form degrades rapidly *in vivo*, with an induction period of only 108 days⁶⁶, and carbonyl groups were detected in unstabilized PP by infrared spectroscopy within 50 – 90 days.⁶⁷ Liebert et al. also tested stabilized PP in the hamster subcutaneous implant model. Oxidation of stabilized PP was observed, but the experiment ended at 100 days, at which time induction had not been observed for stabilized PP filaments. Consequently, the eventual *in vivo* induction time for stabilized PP has not been reported.

Stabilization with antioxidants is not permanent, since the purpose of using antioxidants is to react with any oxidative species (such as ROS) to prevent their reaction with PP.⁶⁸ These stabilizers are distributed throughout the PP, however, and can only protect the polymer if they are in the proper location and only until they are exhausted. The antioxidant package must be optimized for the intended use to achieve maximum service life of the polymer. Neither the Santonox R nor the dilaurothiodipropionate (DLTDP) antioxidant in the Prolene resin used to manufacture Prolene mesh⁶⁹ is designed to protect against the ROS secreted by inflammatory cells *in vivo*. Santonox R is a hindered phenolic antioxidant designed to protect Prolene during high-temperature processing (compounding and extrusion), while DLTDP is designed to protect Prolene from oxidation during long-term storage. Because *in vivo* oxidation and degradation are ongoing in response to the foreign body reaction, the antioxidant will eventually be depleted, resulting in oxidation and degradation of the PP mesh and changes to its properties over time. This cycle of depletion of antioxidants through reaction with ROS followed by the eventual degradation of the surface of the mesh will not stop until all of the mesh is removed, since cracking exposes new surfaces to ROS and the reaction begins anew.⁷⁰

In a manuscript recently accepted for publication, I have reported that TVT, Advantage (Boston Scientific), and Lynx (Boston Scientific) PP meshes, all of which are stabilized with antioxidants, oxidize *in vitro* when incubated in oxidative medium that mimics the reactive oxygen species (ROS) secreted by adherent inflammatory cells.⁷¹ FTIR spectra of

⁶⁴ E. Rene de la Rie. Polymer Stabilizers. A Survey with Reference to Possible Applications in the Conservation Field. *Studies in Conservation* 33:9-22, 1988.

⁶⁵ JM Anderson, A Rodriguez, DT Chang. Foreign Body Reaction to Biomaterials. *Semin Immunol* 20(2): 86–100, 2008.

⁶⁶ Liebert et al. Subcutaneous implants of PP filaments. *JBMR* 10:939-51, 1976.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ ETH.MESH.02268620

⁷⁰ JM Anderson, A Rodriguez, DT Chang. Foreign Body Reaction to Biomaterials. *Semin Immunol* 20(2): 86–100, 2008.

⁷¹ QH Zhao, AK McNally, KR Rubin, M Renier, Y Wu, V Rose-Caprara, JM Anderson, A Hiltner, P Urbanski, K Stokes. Human plasma macroglobulin promotes in vitro oxidative stress cracking of Pellethane 2363-80A: In vivo and in vitro correlations. *J Biomed Mater Res* 27: 379-389, 1993. AE Hafeman, KJ Zienkiewicz, AL Zachman, HJ Sung, LB Nanney, JM Davidson, SA Guelcher. Characterization of degradation mechanisms of biodegradable lysine-derived aliphatic polyurethanes. *Biomaterials* 32(2):419-29, 2011. JL Martin, MK Gupta, JM Page, F Yu, JM Davidson, SA Guelcher, CL Duvall. Synthesis of a Porous, Biocompatible Tissue Engineering Scaffold Selectively Degraded by Cell-Generated Reactive Oxygen Species. *Biomaterials* 35(12):3766-76, 2014. MAP McEnery, S Lu, MK Gupta, KJ Zienkiewicz, JC Wenke, K Kalpakci, D Shimko, CL Duvall, SA Guelcher. Resorbable Poly(thioketal urethane)/Ceramic Composite Bone Cements with Bone-Like Strength. *RSC Advances* 6:109414 - 109424, 2016. JR Martin, CE

PP incubated in oxidative medium for 5 weeks revealed evidence of carbonyl and hydroxyl bonds as predicted by the oxidation mechanism. These findings show that antioxidants cannot stabilize PP mesh indefinitely.

- 6) The effects of oxidation on the stability of Prolene were known to Ethicon prior to launching its SUI and POP devices, but the company did not consider the risks associated with polypropylene oxidation on the stability of Prolene mesh, to the detriment of patients implanted with the devices.**

Ethicon first reported evidence of Prolene oxidation and degradation in internal documents from the 1980s. These documents report evidence of chronic inflammation, oxidation, and degradation (micro-cracking) of Prolene sutures similar to that published in the scientific literature described above. Several relevant studies are reviewed in greater detail below.

In 1981, the depth of surface cracks was measured for explanted cardiovascular and ophthalmic Prolene sutures.⁷² The crack depth varied from 0.5 – 4.5 microns. Another memo in 1983 reported cracking of explanted Prolene sutures.⁷³ One of the explanted sutures showed only 54% of its original strength. The memo noted that the histological evaluation of explanted sutures was consistent with previous studies, characterized by a foreign body reaction and a “degraded acellular infiltrate.” This document also refers to a Prolene Microcrack Committee. Thus, Ethicon was sufficiently aware of Prolene surface cracking to form a committee to investigate the mechanism of cracking.

Two memos written in 1984 investigated the cause of microcracking of explanted PP sutures from both ophthalmic and cardiovascular applications⁷⁴. Sutures that were in the body for more than two years exhibited surface or severe transverse cracks. The thickness of the crack layer ranged from 2 – 5 microns thick. Dr. Peter Moy recognized in a November 5, 1984 report that “oxidative degradation is another mechanism through which transverse cracks may be produced on oriented fibers.”⁷⁵ In an attempt to reproduce the observed cracking *in vitro*, Prolene sutures were incubated in aqueous 30% hydrogen peroxide for up to 1 year. Despite the fact that transverse cracks were not observed, infrared spectroscopy revealed evidence of oxidation products, which prompted Dr. Moy to note that “the possibility of a highly specific *in vivo* oxidation process remains.” These findings are consistent with the foreign body reaction, which produces ROS stronger than hydrogen peroxide.⁷⁶ If treatment with 30% hydrogen peroxide caused oxidation of the PP suture (as reported by Dr. Moy), then ROS secreted by adherent macrophages would also be expected to cause oxidation. Dr. Moy also cited thermal stability and electron microdiffraction data supporting his hypothesis that at least a portion of the cracked layer contained protein. He recommended that an additional study was necessary to test this hypothesis by performing TEM analysis of known oxidized Prolene samples. Another memo dated November 13, 1984, reported that Prolene microcracks were evaluated by

Nelson, MK Gupta, F Yu, KM Hocking, JM Davidson, SA Guelcher, CL Duvall. Local delivery of PHD2 siRNA from ROS-degradable scaffolds to promote diabetic wound healing. *Adv Healthc Mater* 5(21):2751-2757, 2016.

⁷² ETH.MESH.12831405.

⁷³ ETH.MESH.15955438-15955473.

⁷⁴ ETH.MESH.15958452, ETH.MESH.15406978, ETH.MESH.15958470

⁷⁵ ETH.MESH.1595843

⁷⁶ QH Zhao, AK McNally, KR Rubin, M Renier, Y Wu, V Rose-Caprara, JM Anderson, A Hiltner, P Urbanski, K Stokes. Human plasma macroglobulin promotes *in vitro* oxidative stress cracking of Pellethane 2363-80A: *In vivo* and *in vitro* correlations. *J Biomed Mater Res* 27: 379-389, 1993.

Attenuated Total Reflectance (ATR) and FTIR.⁷⁷ These studies found that the cracked Prolene surface is a composite of oxidized polypropylene and adsorbed protein. Surface protein was removed with Soluene treatment, but adsorbed protein remained in the microcracks. Thus, the November 13, 1984 memo by Dan Burkley concludes that the cracked layer contained both oxidized Prolene as well as protein.

In 1985, a series of experiments was proposed, including microscopic FTIR, TEM, and histology, to determine the clinical functionality of cracked sutures, the cracking mechanism, and effects of antioxidant concentration.⁷⁸ Dr. Moy further noted that laboratory experiments had not yet replicated the cracking observed in explants, and proposed a systematic evaluation of explanted Prolene sutures.

In 1987, Professor Guidoin provided Ethicon with his explanted sutures, which had been cleaned using a bleach solution as explained in Mr. Burkley's laboratory notebook.⁷⁹ SEM images of sutures explanted after 8 years revealed evidence of severe cracking. Another cohort of explanted sutures was scraped with a needle and the scrapings tested by calorimetry and FTIR. The waxy scrapings showed a melting point of 147 – 156°C, which is comparable to that of degraded Prolene. Non-degraded Prolene melts over the range 155 – 165°C. Scrapings were also melted on a KBr window to obtain FTIR spectra, which showed peaks associated with β -keto esters known to be formed during PP oxidation. Mr. Burkley noted in his notebook and memo that “no protein species or peptide bonds were suggested.” A memo reporting on a follow-up meeting confirmed the findings that no protein was found on the surface and that Prolene degradation occurred on the surface of the fibers.⁸⁰ Several follow-up studies were proposed, including investigating the relationship between antioxidant concentration and polypropylene degradation and cracking. However, to my knowledge these studies were not performed.

In 1991, a 91-day rat subcutaneous implantation study was performed to assess the tissue reaction for several PP-based surgical meshes, including the Prolene mesh used in the SUI and POP devices.⁸¹ All meshes, including Prolene and Prolene Soft, showed evidence of chronic inflammation at 7 and 91 days. Drs. Barbolt and Hutchinson concluded that all meshes showed evidence of a mild inflammatory reaction and infiltration of connective tissue. Furthermore, images of histological sections revealed evidence of adherent macrophages on the surface of the Prolene fibers.

⁷⁷ ETH.MESH.15958336

⁷⁸ ETH.MESH.15958445

⁷⁹ ETH.MESH.00000367, ETH.MESH.12831391

⁸⁰ ETH.MESH.12831407

⁸¹ ETH.MESH. 02319001, ETH.MESH.01425079

As noted above, Ethicon researchers sought to replicate the surface cracking of Prolene sutures in an *in vitro* experiment. In the 1990s, the effects of the foreign body reaction on biomedical implants were first elucidated. All implantable medical devices are susceptible to the dynamic nature of the environment in which they are implanted. Environmental stress cracking of implanted biomaterials is controlled by three factors: (1) residual stress in the biomaterial, (2) a source of chemical degradation in the body, and (3) the chemical structure of the biomaterial.⁸²

Poly(ether urethane)s used as pacemaker lead insulation are an example of how oxidation of an implanted biomaterial can lead to Environmental Stress Cracking (ESC) and device failure. While poly(ether urethane) elastomers were believed to be biocompatible for many years, they are now known to undergo ESC due to oxidative degradation of the polyether component and subsequent loss in molecular weight.⁸³ As shown in Figure 9, adherent macrophages and FBCGs were responsible for environmental stress cracking of poly(ether urethane)s *in vivo*.⁸⁴ A later study found that *in vivo* stress cracking of this poly(ether urethane) was reproduced *in vitro* by treating pre-stressed polymer specimens with an oxidative medium (10% hydrogen peroxide with 0.10 M cobalt chloride).⁸⁵ The cobalt chloride catalyzes the decomposition of the hydrogen peroxide to form hydroxyl radicals, a form of ROS that attacks the polymer. Under these conditions

simulating the isolated microenvironment between the surface of the biomaterial and the cell, *in vitro* stress cracking was similar in appearance to that observed *in vivo*. Furthermore, infrared spectroscopy showed that ROS participated in the oxidative degradation process.⁸⁶ Thus, oxidative degradation and environmental stress cracking have a synergistic effect on the failure of poly(ether urethane) catheter lead insulation, by which oxidative degradation drives the embrittlement of the polymer surface and its subsequent cracking, which in turn exposes new surfaces of the material to oxidative degradation and

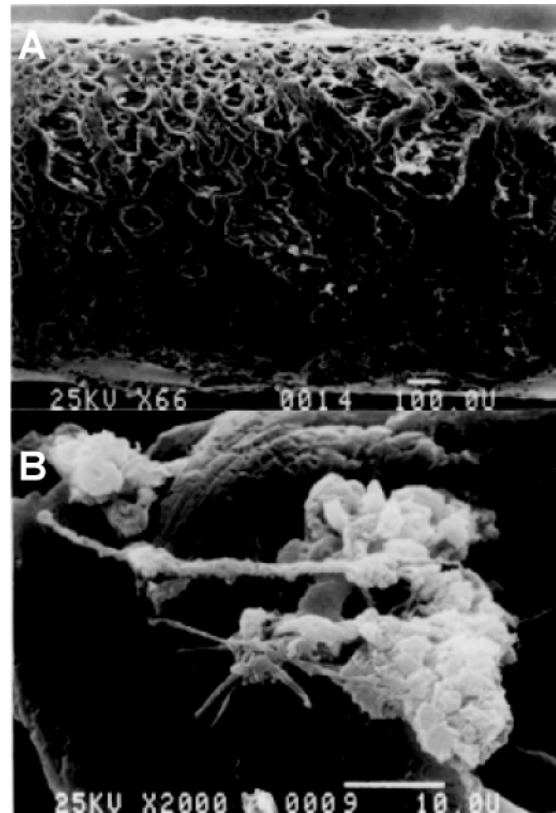


Figure 9. (A) SEM photograph of pre-stressed Pellethane 80A specimen implanted for 5 weeks. The specimen had severe cracking. Original magnification x66. (B) SEM photograph (at higher magnification) of pre-stressed Pellethane 80A specimen implanted for 5 weeks. Cellular adhesion was present. Original magnification x2000. From Zhao et al. JBMR 24:621, 1990.

⁸² JM Anderson et al. Cellular interactions with biomaterials: in vivo cracking of pre-stressed Pellethane 2363-80A. *JBMR* 24: 621-37, 1990.

⁸³ *Id.*

⁸⁴ JM Anderson et al. Cellular interactions with biomaterials: in vivo cracking of pre-stressed Pellethane 2363-80A. *JBMR* 24: 621-37, 1990.

⁸⁵ QH Zhao, AK McNally, KR Rubin, M Renier, Y Wu, V Rose-Caprara, JM Anderson, A Hiltner, P Urbanski, K Stokes. Human plasma macroglobulin promotes in vitro oxidative stress cracking of Pellethane 2363-80A: In vivo and in vitro correlations. *J Biomed Mater Res* 27: 379-389, 1993.

⁸⁶ MJ Wiggins, B Wilkoff, JM Anderson, A Hiltner. Biodegradation of polyether polyurethane inner insulation in bipolar pacemaker leads. *J Biomed Mater Res* 58(3):302-7, 2001.

ultimately clinical device failure.⁸⁷ Similar to poly(ether urethane)s, PP is susceptible to oxidation, which results in chain scission, loss of ductility (e.g., embrittlement),⁸⁸ and degradation, such as pitting, peeling, and cracking⁸⁹. Embrittlement occurs at a very low conversion in the chain scission process, and surface embrittlement of the PP fibers leads to crack initiation. Mechanical stress on the fibers will in turn enhance stress cracking and expose new PP surface to the oxidative environment. I have published two papers in the scientific journal *Biomaterials*, one in 2011 and one in 2014, using the same 20% H₂O₂ /0.1 M cobalt chloride system to measure the oxidative degradation rate of poly(ester urethane) and poly(thioketal urethane) scaffolds. Thus, this *in vitro* oxidative degradation test is well established in the scientific literature, and was available to Ethicon at the time it developed the SUI and POP devices. However, to my knowledge, this test was never done.

Ethicon has also been made aware of the specific risks inherent to using PP in an implantable medical device through the Material Safety Data Sheet (MSDS), which stated that PP is incompatible with strong oxidizers.⁹⁰ As explained above, implanted mesh is exposed to reactive oxygen species, which are strong oxidizers, as a result of the foreign body reaction.

The report from Mesh Repair of Uterovaginal Prolapse meeting in May 1997 noted that an ideal mesh would have lower density compared to that of the TVT to minimize the foreign body reaction.⁹¹ Similar concerns were noted in a discussion document for the design of new mesh for prolapse repair, in which it was noted that the mesh used in the TVT is not the ideal material for anterior prolapse, and that the amount of foreign body should be minimized to reduce the risk of complications.⁹²

The hernia literature also provides evidence that the foreign body reaction alters polypropylene *in vivo*. In a study evaluating non-degradable meshes explanted from 17 patients that had surgery for repair of abdominal wall defects, a foreign body reaction characterized by granulation tissue and inflammatory cells 3 – 24 months post-implantation was seen.⁹³ The PP meshes from this study showed more inflammatory cells and fibroblasts near the mesh interface when compared to PTFE and polyester.

Despite internal and published studies to the contrary, Ethicon documents further indicate that their sales force was instructed to "[r]eassure [surgeons] that PROLENE is proven to be inert and there are hundreds of papers going back 25 years to reinforce this point."⁹⁴ However, Daniel F. Burkley, a Principal Scientist at Ethicon, testified that in his 34 years at the company, he was only familiar with one study that was conducted regarding the changes that occurred due to oxidative degradation of explanted polypropylene suture or

⁸⁷ JM Anderson, A Rodriguez, and DT Chang. Foreign Body Reaction to Biomaterials. *Semin Immunol* 20(2):86–100, 2008.

⁸⁸ Fayolle et al. Initial steps and embrittlement in the thermal oxidation of stabilized polypropylene films. *Polym Degrad Stability* 75:123-9, 2002.

⁸⁹ VV Iakovlev, ET Carey, J Steege. Pathology of Explanted Transvaginal Meshes. *Int. J. Medical, Health, Pharmaceutical and Biomedical Eng.* 8(9):510-513, 2014.

⁹⁰ ETH.MESH.05439518

⁹¹ ETH.MESH.12006257

⁹² ETH.MESH.12009027

⁹³ U Klinge, B Klosterhalfen, M. Muller, V Schumpelick. Foreign Body Reaction to Meshes Used for the Repair of Abdominal Wall Hernias. *Eur J Surg* 165:665–673, 1999.

⁹⁴ ETH.MESH. 00865322

mesh.⁹⁵ Mr. Burkley also testified that this study showed that changes due to oxidation were still progressing after seven years of implantation.⁹⁶

7) PP mesh is not inert and its properties change after implantation, which can lead to adverse events in an implantee; using heavy-weight mesh directly correlates to more PP being exposed to the foreign body reaction and greater changes after implantation, which increases the risk of complications.

The literature has confirmed that the properties of PP mesh change after implantation, causing adverse events like, pain, scarring and inflammation. In addition, Ethicon employees and consultants, both before and after the TVT was launched, have noted that heavy-weight meshes like the TVT comprise significantly more polypropylene than sutures or light-weight meshes, and therefore the foreign body reaction and resulting changes on the surface of the TVT device will be much greater than that for a lightweight mesh or a non-load bearing suture.⁹⁷ These findings are supported by the conclusions drawn by external consultants and Ethicon employees, as well as the available scientific literature reporting PP oxidation in response to cell-secreted ROS and complications associated with the mesh used in the TVT.⁹⁸

More recently, Wood et al. published a comparison of three different explanted synthetic meshes (polypropylene, expanded polytetrafluoroethylene (ePTFE), and polyethylene terephthalate (PET)) from a single patient who had undergone three recurrent ventral hernia repairs.⁹⁹ Implantation times for the meshes were 3 years for the PP and PET meshes and 2 years for the ePTFE mesh. SEM images of explanted PP mesh “showed significant surface cracking” while the PET and ePTFE meshes did not. FTIR analysis also confirmed PP degradation from “free radical formation and oxidation of the polypropylene mesh while *in vivo*.”

The Wood study supports the conclusions published by Clavé et al., which examined explanted pelvic meshes for degradation. Clavé reported that 42% of the explants showed evidence of chronic inflammation, characterized by an infiltrate of mononuclear cells and FGBCs. SEM analysis revealed that the implants were degraded, and that degradation was observed in meshes that had been implanted for at least 3 months.¹⁰⁰

The findings of the Clavé study findings reinforced work done by Costello et al., who reported PP mesh oxidation and embrittlement as being a cause of mesh degradation and

⁹⁵ Burkley Deposition 05/23/2013 P.312:23-313:24

⁹⁶ Burkley Deposition 05/23/2013 P.315:8-13

⁹⁷ Are Meshes With Lightweight Construction Strong Enough?; Jorge L. Holste; *ETHICON GmbH, R&D Europe, D-22841, Norderstedt, Germany*; J. Otto, E. Kaldenhoff, R. Kirschner-Hermanns, T. Muhl, U. Klinge, W.S. Cobb, K.W. Kercher, and B.T. Heniford. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. *Surg Innov.* 12(1):63-9, 2005.

⁹⁸ ETH.MESH.05479411, ETH.MESH.07192929, ETH.MESH.07192412.

⁹⁹ AJ Wood, et al. Materials Characterization and Histological Analysis of Explanted Polypropylene, PTFE, and PET hernia meshes from an Individual Patient. *J Mater Sci Mater Med* 24(4): 1113-1122, 2013.

¹⁰⁰ A Clave, H Yahi, J-C Hammou, S Montanari, P Gounon, H Clave Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. *Int Urogynecol J* 21:261-270, 2010.

complications *in vivo*.¹⁰¹ Costello derived his conclusions from comparisons made between pristine and explanted samples via molecular weight, SEM imaging, and compliance testing. Those authors reported that all three of these methods confirmed that PP mesh had degraded *in vivo*, most likely by oxidation.¹⁰²

Another study investigated 14 explanted hernia mesh samples observed by SEM that 85% of the samples showed evidence of cracking, fissures, and peeling.¹⁰³ After host tissue was removed, the mesh samples remained folded and contracted, evidencing that mesh samples were permanently changed after implantation.

In a 2015 study I co-authored with Dr. Vladimir Iakovlev analyzing 164 explanted PP pelvic meshes, we reported the presence of adherent inflammatory cells expressing the oxidative enzyme myeloperoxidase, degradation of polypropylene, and micro-cracking near the surface of the polypropylene fibers. Degradation of explanted meshes was observed as early as 18 months.¹⁰⁴ Similar findings were reported by Mays et al., who observed oxidative degradation and transverse cracking of explanted PP pelvic mesh.¹⁰⁵

Most importantly, these studies linked complaints of chronic pain and sclerosis to the foreign body reaction to implanted PP mesh and the consequent degradation and micro-cracking near the surface of PP fibers. These principles also apply to PP particles shed from the mesh during implantation, which is consistent with the testimony of Ethicon medical director Piet Hinoul that when particle loss occurs during implantation, the released particles result in inflammation that can cause pain.¹⁰⁶

Large animal models, such as sheep, enable evaluation of PP mesh at longer time points and under conditions more representative of the clinical environment for SUI and POP repair.¹⁰⁷ A pilot study evaluated Prolene mesh implanted vaginally in sheep at 6 and 12 weeks.¹⁰⁸ The incidence of vaginal erosion was observed to be 33%. Macrophages and foreign body giant cells were also observed at 12 weeks. Two more recent studies have investigated differences between PP meshes implanted vaginally and abdominally using a sheep model.¹⁰⁹ PP mesh implanted vaginally showed more contraction and exposures,

¹⁰¹ CR Costello, SL Bachman, SA Grant, DS Cleveland, TS Loy, BJ Ramshaw. Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient. *Surg Innov.* 14:168–176, 2007; CR Costello, SL Bachman, SA Grant. Materials characterization of explanted polypropylene hernia meshes. *J Biomed Mater Res Part B: Appl Biomater* 83B:44-49, 2007.

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ VV Iakovlev, SA Guelcher, R Bendavid. In vivo degradation of polypropylene: microscopic analysis of meshes explanted from 130 patients. *J Appl Biomed Mater Res B: Appl Biomater* 105(2):237-248, 2017.

¹⁰⁵ A Imel, T Malmgren, M Dadmun, S. Gido, J Mays. In vivo oxidative degradation of polypropylene pelvic mesh. *Biomaterials* 73:131-141, 2015.

¹⁰⁶ Trial Testimony of Piet Hinoul, Batiste v. Ethicon, page 26-28

¹⁰⁷ A Feola, M Endo, I Urbankova, J Vlácil, T Deprest, S Bettin, B Klosterhalfen, J Deprest. Host reaction to vaginally inserted collagen containing polypropylene implants in sheep. *Am J Obstet Gynecol* 212:474.e1-8, 2015.

¹⁰⁸ R de Tayrac, A Alves, M Thérin M. Collagen-coated vs noncoated low-weight polypropylene meshes in a sheep model for vaginal surgery. A pilot study. *Int Urogynecol J Pelvic Floor Dysfunct.* 18(5):513-20, 2007.

¹⁰⁹ S Manodoro, M Endo, P Uvin, M Albersen, J Vlácil, A Engels, B Schmidt, D De Ridder, A Feola, J Deprest. Graft-related complications and biaxial tensiometry following experimental

which are both mesh-related complications, than mesh implanted abdominally.¹¹⁰ The authors further noted that the 15% incidence of vaginal exposures in all animals was comparable to that observed clinically, and found that mesh-related complications can be induced by vaginal mesh implantation. Contraction and folding, which have also been associated clinically with pain,¹¹¹ were also observed to be higher for vaginally implanted mesh compared to that implanted abdominally. In a follow-up study, the same authors investigated the effects of a collagen coating on mesh complications and made similar findings.¹¹² Vaginal exposures were observed in 33%, while no abdominal exposures were observed. Macrophages and foreign body giant cells were observed at 60 and 180 days in both vaginal and abdominal meshes. These findings led the authors to conclude that the sheep is an effective model to study complications of vaginal mesh. They further noted that the differential wound healing response and mechanical forces between the vaginal and abdominal wall environments may be responsible for the differences in mesh-related complications between the two implantation sites. Ethicon could have performed a similar sheep study at any time before or after the launch of its any of its mesh products to investigate the incidence of similar mesh-related complications. However, to my knowledge these studies have not been done.

Ethicon documents indicate that the company was aware of the Costello article in 2007, but never considered the effect of PP oxidation during these meshes design or product lifecycle. An Ethicon Medical Affairs employee, Tom Divilio, M.D., indicated that the Costello authors were "challenging our perception of polypropylene as an 'inert' material after implantation." He went on to note that "I think it's important that we understand what they are seeing as this group has a well-funded lab that will be looking at explanted mesh in great volume over the next couple of years and our current concepts are going to be challenged. Would appreciate it if we could think of some study designs that would confirm or refute their assumptions."¹¹³ In 2012, Ethicon responded to a request by a British regulatory agency to explain how the 2010 publication by Clave et al impacts the performance of their products.¹¹⁴ In this document, Ethicon noted "[we] are not aware of any findings that would impact the clinical performance of polypropylene monofilament"¹¹⁵, and that "[p]olymers may be subject to surface degradation by these

vaginal implantation of flat mesh of variable dimensions. *BJOG* 120(2):244-50, 2013.; A Feola, M Endo, I Urbankova, J Vlacil, T Deprest, S Bettin, B Klosterhalfen, J Deprest. Host reaction to vaginally inserted collagen containing polypropylene implants in sheep. *Am J Obstet Gynecol* 212:474.e1-8, 2015.

¹¹⁰ S Manodoro, M Endo, P Uvin, M Albersen, J Vlácil, A Engels, B Schmidt, D De Ridder, A Feola, J Deprest. Graft-related complications and biaxial tensiometry following experimental vaginal implantation of flat mesh of variable dimensions. *BJOG* 120(2):244-50, 2013.

¹¹¹ BT Haylen, RM Freeman, SE Swift, M Cosson, GW Davila, J Deprest et al. An International Urogynecological Association (IUGA)/ International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery. *Neurourol Urodyn* 30:2-12, 2011.

¹¹² Haylen BT, Freeman RM, Swift SE, Cosson M, Davila GW, Deprest J, et al. An International Urogynecological Association (IUGA)/ International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery. *Neurourol Urodyn* 30:2-12, 2011; A Feola, M Endo, I Urbankova, J Vlacil, T Deprest, S Bettin, B Klosterhalfen, J Deprest. Host reaction to vaginally inserted collagen containing polypropylene implants in sheep. *Am J Obstet Gynecol* 212:474.e1-8, 2015.

¹¹³ ETH.MESH. 05588123

¹¹⁴ ETH.MESH. 07226481

¹¹⁵ Id

reactive species, the impact of which has not been clinically assessed."¹¹⁶

In summary, Ethicon scientists reported evidence of chronic inflammation, oxidation, and degradation (micro-cracking) of Prolene in preclinical studies and in human explants. These observations are consistent with the known susceptibility of polypropylene to oxidation outside the body, the known effects of the foreign body reaction on implanted biomaterials, and published studies on explanted PP mesh.¹¹⁷ Despite the fact that Ethicon scientists recommended additional testing to confirm or exclude the oxidation mechanism, I have found no evidence that these tests (which were available to Ethicon during development of the SUI and POP devices) were performed. Consequently, the risks inherent to Prolene oxidation and degradation are detrimental to all of those who have been implanted with the SUI and POP devices.

8) Using autologous fascia lata, allograft, sutures (including polypropylene sutures), or polyvinylidene fluoride (PVDF) mesh, does not present with the same chronic complications associated with the material properties of Ethicon's PP mesh. All of these alternative materials, including using a less dense version of its PP mesh, were available when Ethicon's SUI and POP meshes were first commercialized.

Implantable sutures, including PP sutures, have been used in procedures such as the Burch retropubic urethropexy, autologous and allograft biologic slings, and needle suspension procedures to treat SUI.¹¹⁸ As described above, the foreign body reaction is less persistent for sutures than for polypropylene mesh. In an early study investigating the effects of the foreign body reaction on Prolene sutures implanted in dogs, sutures were surrounded by fibroblasts, collagen, and a few macrophages at 1 – 3 months.¹¹⁹ From 3 months to 2 years, Prolene sutures were encapsulated in collagen with minimal adherent inflammatory cells.¹²⁰ In a later study characterizing the foreign body reaction associated with PP sutures and mesh in a rat abdominal wall model, PP mesh samples showed more adherent inflammatory cells than PP sutures.¹²¹ Recent studies investigating PP mesh explanted from human patients¹²² have reported adherent inflammatory cells near the surface of the PP

¹¹⁶ Id

¹¹⁷ VV Iakovlev*, SA Guelcher, R Bendavid. In vivo degradation of polypropylene: microscopic analysis of meshes explanted from 130 patients. *J Appl Biomater Res: Part B Appl Biomater* 105(2):237-248, 2017.

¹¹⁸ ETH.MESH.00141933; AP Cameron, AM Haraway. The treatment of female stress urinary incontinence: an evidenced-based review. *Open Access Journal of Urology* 3:109-120, 2011; EC Trabuco, CJ Klingele, RE Blandon, JA Occhino, AL Weaver, ME McGree, MA Lemens, JB Gebhart. Burch Retropubic Urethropexy Compared With Midurethral Sling With Concurrent Sacrocolpopexy: A Randomized Controlled Trial. *Obstet Gynecol.* 2016 Oct;128(4):828-35

¹¹⁹ C Mary, Y Marois, MW King, G Laroche, Y Douville, L Martin, R Guidoin. Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery. *ASAIO Journal* 44:199-206, 1998. ML Konstantinovic, E Pille, M Malinowska, E Verbeken, D De Ridder, J Deprest. Tensile strength and host reponse towards different polypropylene implant materials used for augmentation of fascial repair in a rat model. *Int Urogynecol J* 18:619-26, 2007.

¹²⁰ Id.

¹²¹ ML Konstantinovic, E Pille, M Malinowska, E Verbeken, D De Ridder, J Deprest. Tensile strength and host reponse towards different PP implant materials used for augmentation of fascial repair in a rat model. Deprest et al. *Int Urogynecol J* 18:619-26, 2007.

¹²² VV Iakovlev, SA Guelcher, R Bendavid. In vivo degradation of polypropylene: microscopic analysis of meshes explanted from 130 patients. *J Appl Biomater Res: Part B Appl Biomater*, 2015 Aug 28 doi: 10.1002/jbm.b.33502; A Clavé, H Yahi. J-C Hammou, S Montanari, P Gounon, H

fibers at periods of time from 3 months to multiple years. These studies show that the foreign body reaction in response to mesh implantation continues until the mesh is explanted and is dose-dependent (*i.e.*, more PP mesh both in density and amount promotes a more persistent foreign body reaction). Thus, since the foreign body reaction associated with implantable PP sutures is less persistent compared to PP mesh, the use of sutures is preferred from a biomaterials perspective. Furthermore, there is the additional benefit that the suture procedures do not present the risk of mesh-related complications.

Biologic grafts are derived from natural tissue that has been processed to remove cells and antigens that trigger an immune response while preserving the extracellular matrix that stimulates ingrowth of cells and tissue remodeling.¹²³ They are preferred from a biomaterials perspective because they promote a regenerative versus a scarring response. Biologic grafts can be classified into three general categories: (1) autologous fascia lata (autograft), (2) cadaveric fascia or dermal tissue (allograft), and (3) bovine or porcine tissue (xenograft).¹²⁴ In contrast to synthetic grafts, biologic grafts are designed to promote vascularization and tissue remodeling, not scarring.¹²⁵ Biologic grafts are resorbed and replaced by new tissue, thereby eliminating the types of complications associated with PP mesh. In contrast, the foreign body reaction associated with implantation of PP mesh persists for years and is not resolved until the mesh is removed, resulting in oxidation, embrittlement, and degradation. Thus, autografts and allografts eliminate the types of complications associated with the degradation of PP products in the pelvis.

Allografts are medical products that have been prepared from human cadaveric fascia¹²⁶ and human dermis.¹²⁷ Allografts include DuraDerm (Bard, decellularized human dermis), FasLata (Bard, cadaveric fascia lata), and Repliform (Boston Scientific, decellularized human cadaveric dermis). They are indicated for repair or replacement of damaged or inadequate integumental tissue, such as in the treatment of urinary incontinence, and for pelvic floor reinforcement or other conditions resulting from inadequate or damaged integumental tissue. Dermal allografts such as Repliform are processed under unique conditions to maintain the structure of the collagen and stimulate fibroblast remodeling of the extracellular matrix, resulting in cellular infiltration, vascularization, and new tissue ingrowth to achieve regenerative repair with reduced scarring and risk of exposure.¹²⁸ In a prospective series of 253 patients with SUI treated with a transvaginal sling using a Repliform cadaveric human dermal allograft and a bone anchor fixation kit, 234 of 253 patients were followed up at an average of 18 months.¹²⁹ 78% of the patients were cured or

Clavé. PP as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. *Int Urogynecol J* 21:261-270, 2010; A Imel, T Malmgren, M Dadmun, S. Gido, J Mays. In vivo oxidative degradation of polypropylene pelvic mesh. *Biomaterials* 73:131-141, 2015; AL Nolfi, BN Brown, R Liang, SL Palcsey, MJ Bonidie, SD Abramowitch, PA Moalli. Host response to synthetic mesh in women with mesh complications. *Am J Obstet Gynecol* 215:206.e1-8, 2016.

¹²³ ETH.MESH.00141933

¹²⁴ ETH.MESH.04941016

¹²⁵ ETH.MESH.04941016

¹²⁶ SL Brown, FE Govier. Cadaveric versus autologous fascia lata for the pubovaginal sling: surgical outcome and patient satisfaction. *J Urology* 164, 1633—1637, 2000.

¹²⁷ S Crivellaro, JJ Smith, E. Kocjancic, JF Bresette. Transvaginal sling using acellular human dermal allograft: safety and efficacy in 253 patients. *J Urology* 172, 1374—1378, 2004.

¹²⁸ ETH.MESH.00141933

¹²⁹ S Crivellaro, JJ Smith, E. Kocjancic, JF Bresette. Transvaginal sling using acellular human dermal allograft: safety and efficacy in 253 patients. *J Urology* 172, 1374—1378, 2004

improved according to patient questionnaires. Most significantly, there were no cases of vaginal or urethral erosion.¹³⁰

Polyvinylidene fluoride (PVDF) is a synthetic polymer manufactured by polymerization of vinylidene difluoride. As shown in Figure 10, PVDF is one of the least readily oxidized polymers, while PP is one of the most.¹³¹ PVDF sutures are used extensively in orthopaedic and cardiovascular surgery.¹³² In 1988, Mary et al. compared PROLENE to PVDF sutures in a canine thoracoabdominal bypass model for 10 periods of implantation ranging from 4 hours to 2 years.¹³³ PROLENE sutures explanted after 1 or 2 years implantation time showed evidence of surface cracking by SEM. In contrast, PVDF sutures explanted after 1 or 2 years did not show evidence of surface cracking when analyzed by SEM. These findings led the authors to conclude that PVDF “may be more biostable than polypropylene in the long term.” In another long-term study, PVDF sutures preserved 92.5% of their initial strength after 9 years of implantation compared to 54.4% for PP sutures due to oxidation of the PP.¹³⁴

In 1985, Ethicon implanted 24 beagles with PROLENE, PVDF, Ethilon, and Novafil sutures implanted subcutaneously in a 10-year study. Sutures were explanted at 5 or 7 years (the study was ended prematurely due to the unexpected death of one of the dogs at 6 years and 10.5 months). At 5 years, surface cracking was observed by SEM for 2 of the 5 PROLENE sutures, while surface cracking was not observed for any of the PVDF sutures. At 7 years, PROLENE sutures explanted from 3 of the 7 sites showed surface cracking by SEM, while only 1 of the 6 PVDF sutures showed evidence of surface cracking. The authors noted that only PDVF and Novafil sutures showed only marginal surface changes. The authors concluded that “degradation in PROLENE is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking.”¹³⁵ These findings are consistent with those from the Mary et al. study¹³⁶ and the resistance of PVDF to oxidative degradation.¹³⁷

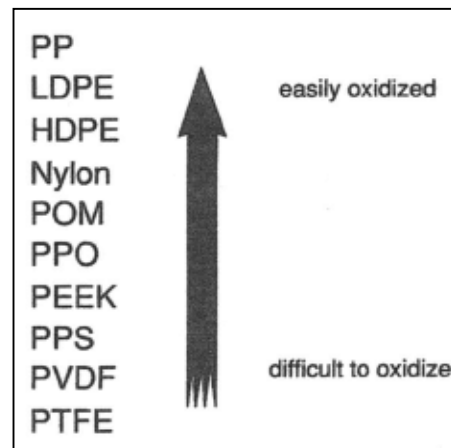


Figure 10. Tendency of various polymers to undergo oxidation. Reproduced from Compositional and Failure Analysis of Polymers, 2000, p.398, 426.

¹³⁰ SL Brown, FE Govier. Cadaveric versus autologous fascia lata for the pubovaginal sling: surgical outcome and patient satisfaction. *J Urology* 164, 1633—1637, 2000. BJ Flynn, WT Yap. Pubovaginal sling using allograft fascia lata versus autograft fascia for all types of stress urinary incontinence: 2-year minimum followup. *J Urology* 167, 608—612, 2002.

¹³¹ Compositional and Failure Analysis of Polymers, 2000, p. 398, 426.

¹³² K Junge, M Binnebösel, KT von Trotha, R Rosch, U Klinge, UP Neumann, PL Jansen. Mesh biocompatibility: effects of cellular inflammation and tissue remodeling. *Langenbecks Arch Surg* 2011, DOI 10.1007/s00423-011-0780-0.

¹³³ C Mary, Y Marois, MW King, G Laroche, Y Douville, L Martin, R Guidoin. Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and polypropylene Sutures Used in Vascular Surgery. *ASAIO Journal* 44:199-206, 1998.

¹³⁴ G Laroche, Y Marois, E Schwarz, et al. Polyvinylidene fluoride monofilament sutures: can they be used safely for long-term anastomoses in the thoracic aorta? *Artif Organs* 19 (11):1190–9, 1995.

¹³⁵ ETH.MESH.05453719; ETH.MESH.11336474

¹³⁶ C Mary, Y Marois, MW King, G Laroche, Y Douville, L Martin, R Guidoin. Comparison of

In an Ethicon-funded study, two PVDF hernia meshes were compared to PROLENE to assess differences in function tissue response. Mesh was implanted in a rat abdominal wall inlay model for 3, 14, 21, 42 and 90 days.¹³⁸ PVDF meshes showed significantly decreased inflammatory and fibrous tissue reactions compared to PROLENE mesh. After day 3, the PVDF meshes showed a significantly lower volume fraction of inflammatory cells compared to PROLENE mesh. PROLENE mesh showed an increased volume fraction of granulocytes, macrophages, and fibroblasts compared to PVDF meshes. In contrast, PVDF meshes showed a higher volume fraction of foreign body giant cells, which are indicative of a primarily chronic response. The authors further noted that PVDF meshes showed similar cellular responses despite their differences in weight. The moderate foreign body reaction observed for the PVDF meshes showed fewer granulocytes, macrophages, and fibroblasts, and a greater number of foreign body giant cells. Based on these findings, the authors concluded that both PVDF meshes induced significantly lower inflammation and fibrosis compared to PP mesh, and that PVDF is a possible alternative material to PP.

Internal Ethicon documents reveal that Ethicon employees and consultants were aware of the improved biostability of PVDF compared to PP. In 2007, Dr. Kersin Spychaj, an Ethicon employee, wrote a memo on mesh shrinkage based on a literature review.¹³⁹ Dr. Spychaj noted that PP induces a rapid and acute inflammatory response, and concluded that the ideal mesh induces a “mild but not excessive FBR.” Also in a 2007 email, Dr. Dieter Engel, an Ethicon employee, stated that Ethicon will move to Pronova (a copolymer of PVDF and hexafluoropropylene) as the future material for mesh due to its reduced foreign body reaction compared to PROLENE.¹⁴⁰ In a 2011 interview on mesh erosion conducted by PA consulting group on behalf of Ethicon, Professor Klosterhalfen noted that PP meshes degrade over time, and that Dynamesh, a PVDF mesh manufactured by FEG Textiltechnik, is one of the most stable materials he has seen.¹⁴¹ Also in 2011, the PA Consulting Group issued a report on mesh exposure in the pelvic floor.¹⁴² They noted that investigation of the causes of mesh exposure is “further complicated by known factors, such as the propensity of polypropylene (PP) to suffer degradation.” They further noted that while PP has a long history of use, it is subject to degradation, which has been observed in animal studies. The authors proposed PVDF as an alternative polymer for manufacture of pelvic mesh.

FACTS OR DATA CONSIDERED IN FORMING OPINIONS

The opinions and the bases for those opinions are set forth above. In addition to my knowledge, skill training and experience as an engineer, the following depositions of Ethicon employees and the exhibits thereto were supplied to me: Cliff Volpe, Piet Hinoul, David Robinson, Sunny Rah, Aaron Kirkemo, Sean O'Bryan, Scott Ciarrocca, Vincenzo Zaddem, Elizabeth Vailhe, Christophe Vailhe, Joerg Holste, Boris Batke, Daniel Burkley, Thomas Barbolt, Brigitte Hellhammer, Juergen Trzewik, Martin Weisberg, Axel Arnaud, Dan Smith, Prof Thomas Muehl, Dr. Bernd Klosterhalfen, Kevin Ong, Whenxin Zheng,

the In Vivo Behaviour of Polyvinylidene Fluoride and polypropylene Sutures Used in Vascular Surgery. *ASAIO Journal* 44:199-206, 1998.

¹³⁷ Compositional and Failure Analysis of Polymers, 2000, p. 398, 426.

¹³⁸ U Klinge, B Klosterhalfen, AP Ottingerc, K Junge, V Schumpelick. PVDF as a new polymer for the construction of surgical meshes. *Biomaterials* 23 (2002) 3487–3493.

¹³⁹ ETH.MESH.01218361.

¹⁴⁰ ETH.MESH.05447475.

¹⁴¹ ETH.MESH.07192412.

¹⁴² ETH.MESH.07192412.

Daniel Sexton, and Jeffrey Brent.

I have also considered the following material identified in Exhibit B.

In addition, the following reports were supplied to me: Dr. Howard Jordi, Dr. Russell Dunn, Prof Thomas Muehl, Prof. Bernd Klosterhalfen, Thomas Barbolt, Dr. Wenxin Zheng, and B. Todd Heniford, M.D. The findings of these experts are consistent with my opinions.

COMPENSATION

A fee sheet has been attached as Exhibit C.

**LISTING OF CASES IN WHICH TESTIMONY HAS BEEN GIVEN IN
THE LAST FOUR YEARS**

- IN RE PELVIC MESH AMS LITIGATION, SERRANO ET AL – SEPTEMBER 2013
- IN RE PELVIC MESH ETHICON LITIGATION, HUSKEY ET AL. - MARCH 2014
- IN RE PELVIC MESH BOSTON SCIENTIFIC LITIGATION, ALBRIGHT ET AL – JULY 2014
- IN RE PELVIC MESH BOSTON SCIENTIFIC LITIGATION, CARDENAS ET AL – AUGUST 2014
- IN RE PELVIC MESH ETHICON LITIGATION, HUSKEY ET AL – AUGUST 2014
- IN RE PELVIC MESH BOSTON SCIENTIFIC LITIGATION, BARBA ET AL - FEBRUARY 2014
- IN RE PELVIC MESH BARD LITIGATION, CORRIVEAU ET AL – NOVEMBER 2014
- IN RE PELVIC MESH BOSTON SCIENTIFIC LITIGATION, FRANKUM ET AL – DECEMBER 2014
- IN RE PELVIC MESH ETHICON LITIGATION, PERRY - DECEMBER 2014
- IN RE PELVIC MESH ETHICON LITIGATION, PERRY – JANUARY 2015
- IN RE PELVIC MESH AMS LITIGATION, KILGORE ET AL - FEBRUARY 2015
- IN RE PELVIC MESH BOSTON SCIENTIFIC LITIGATION, BARBA ET AL - MAY 2015
- IN PELVIC MESH ETHICON LITIGATION, BRYANT ET AL – SEPTEMBER 2015
- IN RE PELVIC MESH BOSTON SCIENTIFIC LITIGATION, CARLSON ET AL – OCTOBER 2015
- IN RE PELVIC MESH ETHICON LITIGATION, WAVE 1 – MARCH 2016
- IN RE PELVIC MESH BOSTON SCIENTIFIC LITIGATION, VESTER ET AL – OCTOBER 2016
- IN PELVIC MESH BARD LITIGATION – APRIL 2017



Scott Guelcher, Ph.D.
Guelcher Consulting, LLC

EXHIBIT C



Oxidation and degradation of polypropylene transvaginal mesh

Anne D. Talley^a, Bridget R. Rogers^a, Vladimir Iakovlev^{b,c}, Russell F. Dunn^{a,d} and Scott A. Guelcher^{a,e,f}

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ABSTRACT

Polypropylene (PP) transvaginal mesh (TVM) repair for stress urinary incontinence (SUI) has shown promising short-term objective cure rates. However, life-altering complications have been associated with the placement of PP mesh for SUI repair. PP degradation as a result of the foreign body reaction (FBR) has been proposed as a contributing factor to mesh complications. We hypothesized that PP oxidizes under *in vitro* conditions simulating the FBR, resulting in degradation of the PP. Three PP mid-urethral slings from two commercial manufacturers were evaluated. Test specimens ($n = 6$) were incubated in oxidative medium for up to 5 weeks. Oxidation was assessed by Fourier Transform Infrared Spectroscopy (FTIR), and degradation was evaluated by scanning electron microscopy (SEM). FTIR spectra of the slings revealed evidence of carbonyl and hydroxyl peaks after 5 weeks of incubation time, providing evidence of oxidation of PP. SEM images at 5 weeks showed evidence of surface degradation, including pitting and flaking. Thus, oxidation and degradation of PP pelvic mesh were evidenced by chemical and physical changes under simulated *in vivo* conditions. To assess changes in PP surface chemistry *in vivo*, fibers were recovered from PP mesh explanted from a single patient without formalin fixation, untreated ($n = 5$) or scraped ($n = 5$) to remove tissue, and analyzed by X-ray photoelectron spectroscopy. Mechanical scraping removed adherent tissue, revealing an underlying layer of oxidized PP. These findings underscore the need for further research into the relative contribution of oxidative degradation to complications associated with PP-based TVM devices in larger cohorts of patients.

ARTICLE HISTORY

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KEYWORDS

Degradation; oxidation; polypropylene; transvaginal mesh

Introduction

Surgical treatment options for stress urinary incontinence (SUI) and pelvic organ prolapse (POP) include reconstruction of connective tissue with biological or synthetic grafts. The

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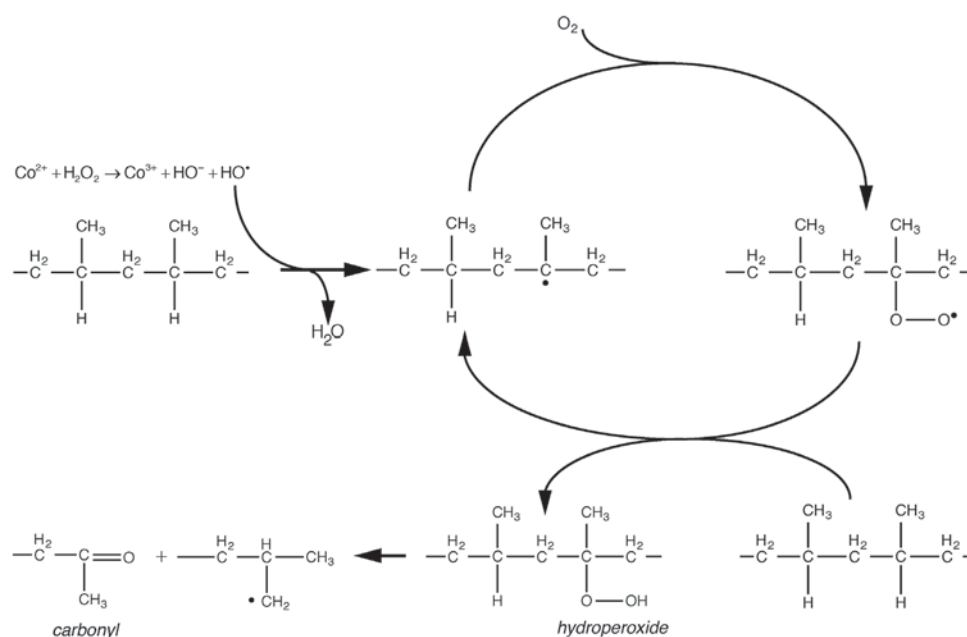
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Figure 1. Proposed mechanism of PP oxidation.

most common synthetic grafts are non-resorbable polypropylene (PP) meshes, which have shown promising results in some studies [1,2]. While PP was initially considered inert *in vivo*, despite the fact that it is readily oxidized outside the body [3], its use in transvaginal mesh (TVM) implantations has recently been associated with high complication rates [4–7]. Complications arising from mesh implantation can lead to pain, graft exposure, and specific urinary symptoms [6,8].

Several studies have reported that PP mesh explanted from patients following graft complications revealed evidence of degradation, such as cracking, pitting, and flaking. In the first study explant study, SEM analysis of mesh removed from 100 patients revealed evidence of degradation for the majority of PP monofilament meshes implanted for more than 3 months [9]. In a more recent study, microscopic analysis of 164 explanted TVM devices revealed a layer of degraded PP, which grew thicker with implantation time [10]. Degradation and microcracking of the PP fibers were observed by conventional light microscopy as early as 18 months post-implantation.

Oxidation has been proposed as a potential mechanism of PP degradation *in vivo* [9,11–13]. PP oxidation proceeds through a stable hydroperoxide ($-\text{COOH}$) intermediate prior to chain scission and the formation of a carbonyl ($-\text{C}=\text{O}$) end group (Figure 1) [14,15], resulting in a reduction in PP molecular weight, loss of ductility, embrittlement, and crack formation [16]. In a recent study, TVM explanted from 11 patients showed evidence of PP oxidation using FTIR and SEM with X-ray dispersive spectroscopy (SEM/EDS), which distinguished oxidized PP from adsorbed biological material [12]. Oxidation of PP fibers was accompanied by transverse cracking of PP fibers, providing evidence of embrittlement.

Secretion of reactive oxygen species (ROS) by adherent inflammatory cells has been reported to promote oxidative degradation of implanted biomaterials [17–20]. Implantation

Table 1. Physical properties of mid-urethral slings evaluated in this study. All slings are macroporous monofilament Type I meshes with pore sizes >75 μm .

Product	Abbrev.	Manu-facturer	Weight (g m^{-2})	Pore size (μm)	Filament Size (mm)	Mesh thick- ness (mm)
Gynecare TVT™ retropubic system	TVT	Ethicon	105	1379	0.15	0.63
Advantage™ transvaginal Mid-urethral sling system	ADV	Boston Scientific	100	1182	0.15	0.66
Lynx™ suprapu- bic mid-ure- thral sling system	LYNX	Boston Scientific	100	1182	0.15	0.66

of TVM induces a chronic inflammatory response characterized by adherent macrophages and giant cells that persists for years after implantation [8–10,21]. Recent studies have reported that the foreign body reaction (FBR) is pro-inflammatory, characterized by predominantly M1 macrophages [21] and significantly higher expression of MMP-9 [8]. Furthermore, elevated MMP-9 expression was found to correlate with mesh exposure.

In the present study, we hypothesized that PP mesh oxidizes in response to ROS secreted by adherent inflammatory cells. To test our hypothesis, we investigated the oxidative degradation of three commercial mid-urethral slings (MUSs) *in vitro* using an oxidative medium comprising 20% hydrogen peroxide (H_2O_2) and 0.1 M cobalt chloride (CoCl_2), which react to form hydroxyl radicals (OH^\bullet) [18,22] that attack the tertiary C–H bond in the PP backbone (Figure 1). This *in vitro* assay recapitulates the oxidative microenvironment between an adherent macrophage and the PP surface [17]. MUS products, which are stabilized with antioxidants to protect against oxidation during high-temperature processing and long-term storage [20], were evaluated to test the hypothesis that the antioxidants do not prevent eventual oxidation and degradation under simulated *in vivo* conditions. Oxidation of PP mesh was measured by Fourier Transform Infrared Spectroscopy (FTIR), and degradation was assessed by Scanning Electron Microscopy (SEM). We also characterized PP mesh fibers explanted from a single patient by X-ray photoelectron spectroscopy (XPS) to analyze PP oxidation *in vivo*. The advantage of the XPS technique is that the composition of atoms and chemical bonds near the surface can be determined, which enables oxidized PP to be differentiated from tissue.

Materials and methods

Materials

Three commercial MUSs were obtained from two device manufacturers: Gynecare TVT™ Retropubic System (Ethicon, Somerset, New Jersey), Advantage™ Transvaginal Mid-Urethral Sling System (Boston Scientific, Marlborough, MA), and Lynx™ Suprapubic Mid-Urethral Sling System (Boston Scientific). All slings are macroporous monofilament Type I meshes with pore sizes >75 μm . Other mesh properties are summarized in Table 1. For the oxidative media, CoCl_2 was obtained from Sigma-Aldrich (St Louis, MO) and 30 wt.% H_2O_2 from Fisher Scientific (Pittsburgh, PA).

Table 2. *In vitro* study design.

Time week	FTIR		SEM	
	Specimens	Regions/Specimen	Specimens	Regions/Specimen
0	3	2	1	5–13
1	3	2	0	N/A
3	3	2	0	N/A
4	3	2	0	N/A
5	3	2	1	7–15

In vitro oxidation

For each of the three products listed in Table 1, 17 MUS specimens (approximately 6–7 mg, 1.1 cm by 0.6 cm) were prepared. The study design is listed in Table 2. Thirteen specimens were incubated at 37 °C for up to 5 weeks in oxidative media composed of 0.1 M CoCl₂ in 20 wt.% H₂O₂, which simulates the privileged microenvironment between an adherent macrophage and the PP surface [18–20,22,23]. In this medium, the H₂O₂ and cobalt ions react to form hydroxyl radicals (OH•, Figure 1) [22]. Samples were submerged by being weighted down using glass beads and were incubated at 37 °C in the oxidative medium on a shaker. At each time point (week 1, 3, 4, or 5), 3 specimens were removed, washed in DI water, and dried. FTIR analysis was performed to test for the presence of hydroxyl (–OH) groups present in the hydroperoxide intermediate and for terminal carbonyl (–C=O) end groups. Two locations on each of the 3 MUS mesh specimens were tested via FTIR, giving $n = 6$ replicates at each time point. At 5 weeks, one specimen was removed, washed in DI water, and dried for SEM analysis to identify evidence of oxidative degradation, such as pitting, flaking, and cracking. The oxidative media was changed every 3–4 days (3). Four pristine mesh specimens (three for FTIR and one for SEM) not incubated in oxidative medium were assessed as the 0-week group.

Fourier transform infrared spectroscopy (FTIR)

FTIR spectra were obtained using a Thermo Electron IR200 spectrometer. FTIR peak areas were quantified using Omnic 8.3 software. The area under the hydroxyl peak was integrated over 3600–3050 cm^{–1}. Carbonyl peaks were integrated from 1750 to 1500 cm^{–1}. For each spectrum, the baseline was manually corrected around the peak of interest in the case of any baseline shifts.

Scanning electron microscopy (SEM)

Meshes were examined for degradation at 5 weeks, since at this time point evidence of significant oxidation was observed in the FTIR spectrum. At 5 weeks, one mesh specimen was removed from oxidative media, dried at room temperature, and sputter-coated for 45 s using a Cressington Q108 sputter coater, which deposited gold at a 30-mA current. One mesh specimen that was not incubated in oxidative medium was imaged as a control (0 weeks group). Specimens were imaged using SEM (Hitachi S-4200 SEM) at a voltage of 1 kV. A total of 5–15 images were taken of each specimen. Images were taken at low (40–150X) and medium (150–1000X) magnification to identify regions of the mesh that showed evidence of degradation. High-magnification images (1000–2000X) were taken of 5-week specimens

to show surface degradation, characterized by flaking (feature size $>10\ \mu\text{m}$), peeling (feature size $>10\ \mu\text{m}$), or pitting ($>1\ \mu\text{m}$ deep). These features were not present on control (0 weeks) mesh samples, which showed only specks $<1\ \mu\text{m}$ deep, spots, and longitudinal striations on the surface.

X-ray photoelectron spectroscopy (XPS) of explanted PP mesh

After approval of the St. Michael's Hospital Research Ethics Board, an explanted American Medical Systems PP MUS specimen from a single patient, preserved dry without formalin and received by the pathology department at St. Michael's, was selected for testing. The mesh was explanted for complications other than mucosal erosion. A part of the specimen was processed for histology, which showed evidence of a FBR in response to implantation of the mesh with no superimposed acute (bacterial) inflammation. Tissue-free fibers of the PP mesh at the specimen edges were separated from the specimen using ophthalmic tweezers and scissors. To assess the effects of mechanical cleaning on the surface chemistry of the fibers, three distinct regions were characterized by XPS: (1) one area of interest (AOI) on untreated fibers showing no evidence of residual tissue by microscopy (Untreated residue-free group), (2) one AOI on the same untreated fibers showing evidence of residual tissue (Untreated residue-present group), and (3) one AOI on scraped fibers in which the outer layer was mechanically removed using tweezers and a scalpel blade under a dissection microscope (Scraped group). Five Untreated fibers and five Scraped fibers were analysed by XPS with a PHI Versaprobe using Al $K\alpha$ x-rays (1486 eV). A 20- μm diameter X-ray spot (AOI) was rastered across the analysis area, and a take-off angle of 45 degrees off sample normal was used. Pass energies of 187.7 and 23.5 eV were used for the survey and high-resolution acquisitions, respectively. Charge neutralization was accomplished using 1.1 eV electrons and 10 eV Ar^+ ions. The energy scales of the high-resolution spectra were calibrated to place $-\text{CH}_2-$ bonding in the carbon 1s spectrum at 284.8 eV. Relative atomic concentrations were calculated using peak areas and handbook sensitivity factors.

Statistical analysis

For each *in vitro* FTIR data-set ($n = 6$) measured for a specific type of mesh at a specific time point, the one-sample Komogorov-Smirnov test failed to reject the null hypothesis that the data-set came from a standard normal distribution ($\alpha < 0.05$). Thus, the data were assumed to be normally distributed. Carbonyl and hydroxyl peak areas were plotted as mean \pm SEM and analyzed using a two-way ANOVA for mesh composition and time. Pairwise comparisons were performed by a Tukey's honestly significant difference (HSD) test.

For each *in vivo* XPS data-set ($n = 5$) measured for a specific surface treatment (Untreated residue-free, Untreated residue-present, and Scraped), the one-sample Komogorov-Smirnov test failed to reject the null hypothesis that the data-set came from a standard normal distribution ($\alpha < 0.05$). Thus, the data were assumed to be normally distributed. Surface atomic concentrations, atomic ratios, and C1s bonding concentrations were plotted as mean \pm SD and analyzed by a one-way ANOVA and Tukey's HSD test for pairwise comparisons. For all FTIR and XPS analysis, the significance level was defined as $p < 0.05$.

Results

In vitro oxidation assessed by FTIR spectroscopy

FTIR spectra taken after 0 weeks immersion time showed minimal hydroxyl ($-OH$) or carbonyl ($-C=O$) peaks for each of the PP mesh devices (Figure 2). However, after 5 weeks incubation time, FTIR spectra of all three meshes showed the appearance of both $-OH$ and $-C=O$ groups, which indicates that the PP had oxidized, resulting in the formation of hydroperoxide ($-COOH$, gray arrow) intermediate and terminal $-C=O$ (black arrow) groups (Figure 2). A two-way ANOVA with Tukey's HSD test for pairwise comparisons showed that the areas of the hydroxyl and carbonyl peaks at 5 weeks were significantly ($p < 0.05$) higher than those at the other time points. No significant differences between the three mesh groups were observed at any time point. These findings confirm our hypothesis that PP mesh oxidizes in response to ROS, such as hydroxyl radicals.

Surface degradation assessed by SEM

Low- ($40\text{--}60\times$) magnification SEM images at 0 weeks (untreated control, Figure 3(A) top row) and at 5 weeks (Figure 3(B) top row) revealed the knitted monofilament structure of the meshes. Medium- ($800\text{--}1000\times$) magnification images showed dark spots and longitudinal striations along the axis of extrusion as well as specks $<1\text{ }\mu\text{m}$ deep (Figure 3(A), bottom row). No evidence of features associated with surface degradation was observed, such as flaking ($>10\text{ }\mu\text{m}$ long), peeling ($>10\text{ }\mu\text{m}$ long), or pitting ($>1\text{ }\mu\text{m}$ deep). In contrast, medium-magnification SEM images of PP mesh incubated for 5 weeks in oxidative media (Figure 3(B) middle row) revealed evidence of pits $>1\text{ }\mu\text{m}$ deep (black arrows), peeling flakes $>10\text{ }\mu\text{m}$ long (double white arrows), and shallow craters $>10\text{ }\mu\text{m}$ long (white arrows) on the surface. High- ($1500\text{--}2000\times$) magnification images showed that small pits $<5\text{ }\mu\text{m}$ in diameter and $>1\text{ }\mu\text{m}$ deep had formed on the surface of the mesh. These pits were observed in all fields of view examined at medium and high magnification. Some regions of the mesh showed evidence of larger scale features, such as detachment of peeling flakes $>10\text{ }\mu\text{m}$ (double white arrows) from the surface, resulting in the formation of shallow craters (white arrows). These observations at 5 weeks are consistent with our hypothesis that PP mesh oxidizes in response to ROS, resulting in PP embrittlement and surface degradation (16).

Oxidation of explanted PP mesh

A survey spectrum was collected from each of the Untreated residue-free, Untreated residue-present, and Scraped AOIs analyzed. An X-ray-induced secondary electron micrograph shows the AOI (white box in Figure 4(A)) analyzed on representative Untreated residue-free and Scraped samples (the complete set of images, spectra, and surface composition data for all groups are presented in the Supplemental Data). A one-way ANOVA with Tukey's HSD test for pairwise comparisons showed no significant ($\alpha < 0.05$) differences in surface atomic concentrations, atomic ratios, or C1s bonding between the residue-free and residue-present AOIs on Untreated fibers. This finding suggests that the AOIs tested are representative of the fiber (within the error of the measurement), since the two AOIs that appeared visibly different showed no significant differences in surface composition. After

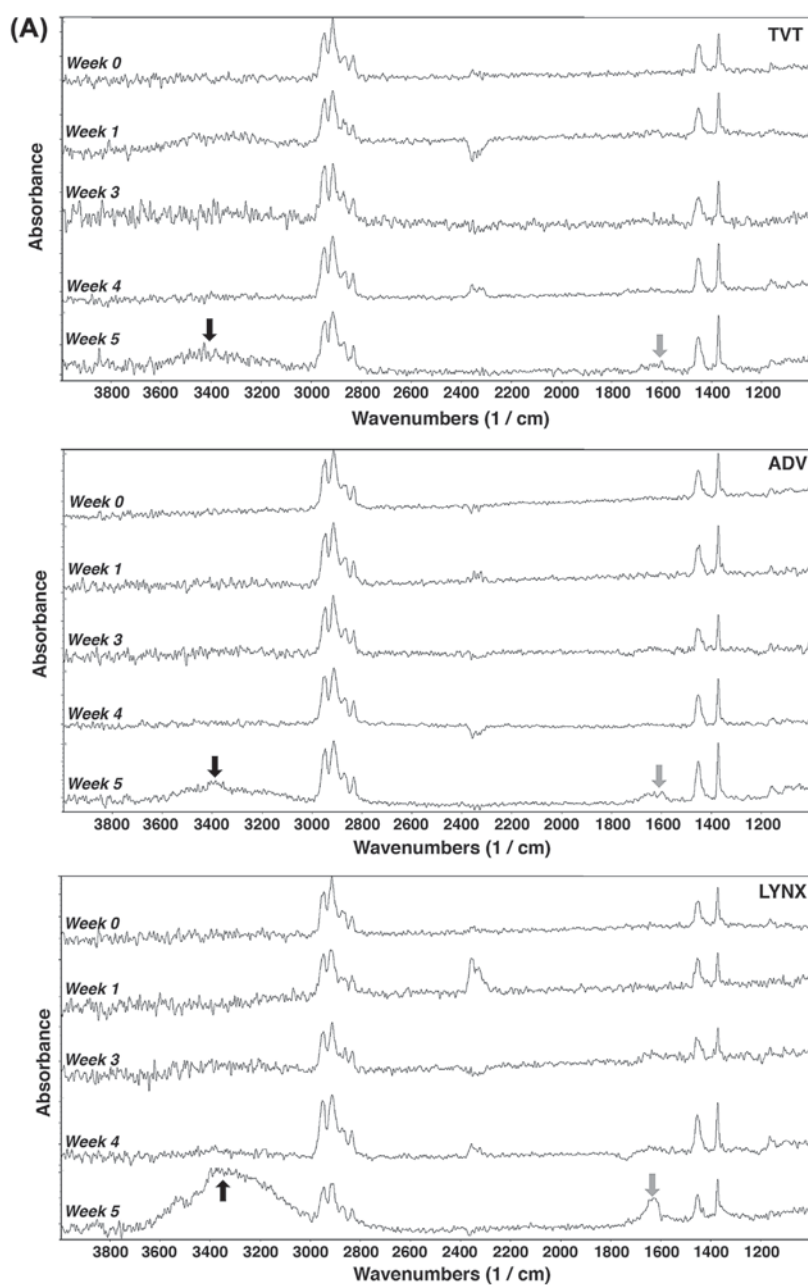


Figure 2. Effects of incubation time in oxidative medium on the composition of PP mesh assessed by FTIR spectroscopy. (A) FTIR spectra of PP mesh samples incubated in oxidative medium for up to 5 weeks at 37 °C. Carbonyl (-C=O , black arrow) and hydroxyl (-OH , gray arrow) peaks increase with time for each mesh. (B–C) Plots of the area of the (B) -OH peak (integrated over $3600\text{--}3000\text{ cm}^{-1}$) and (C) -C=O peaks (integrated over $1750\text{--}1500\text{ cm}^{-1}$) show a significant increase in carbonyl and hydroxyl peak areas at week 5. Note: *Denotes statistical significance ($p < 0.5$).

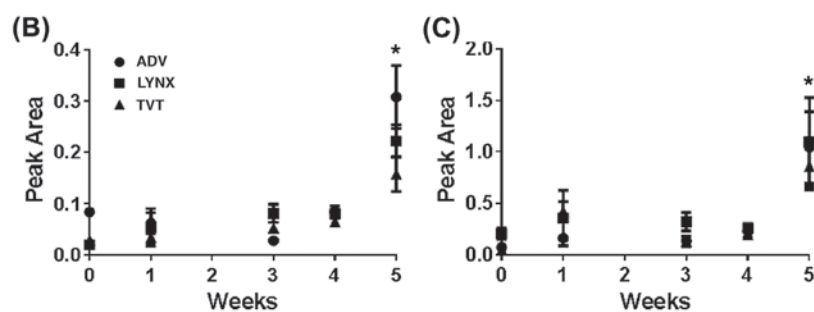


Figure 2. (Continued).

scraping, the atom-% C significantly increased, the atom-% O significantly decreased, and the atom-% N significantly decreased ($p < 0.05$, Figure 4(B)). Consequently, the atomic ratios O:C, N:C, and N:O significantly decreased after scraping ($p < 0.05$, Figure 4(C)). While all the Untreated samples showed nitrogen on the surface, only one of the Scraped samples, which were mechanically debrided to remove oxidized PP and protein from the surface, showed nitrogen. In contrast, all of the Scraped fibers exhibited oxygen on the surface, which is attributed to the presence of residual oxidized PP on the surface after scraping. Thus, mechanical scraping removed adherent tissue to reveal an underlying layer of oxidized PP in this specific patient explant. These findings highlight the potential of XPS analysis of mechanically scraped fibers from explanted mesh without formalin fixation for assessing oxidation of PP mesh *in vivo*.

High-resolution carbon 1s (C1s) spectra from Untreated and Scraped fibers are shown in Figure 4(D). These spectra were curve-fitted to extract the contributions of different carbon bonding configurations present in the spot [24]. All Untreated fibers exhibited some fraction of the carbon present bonded in carbonyl and hydroperoxide configurations. One-way ANOVA with Tukey's HSD test for pairwise comparisons showed that scraping significantly ($\alpha < 0.05$) reduced the percent of C1s bonding configurations comprising carbonyl and hydroperoxide bonds (Figure 4(E)). However, all scraped fibers showed evidence of oxygen on the surface: two showed carbonyl bonding and four showed hydroperoxide bonding. Since nitrogen was observed on the surface of only one scraped fiber, the carbonyl and/or hydroperoxide bonds present on the scraped fibers cannot be attributed to protein adsorption. Thus, the data in Figure 4(D) and (E) reveal evidence of carbonyl and hydroperoxide peaks on Untreated residue-free and Scraped fibers that are consistent with the oxidation reaction mechanism for PP. Explanted mesh from only one patient was evaluated, which precludes statistical analysis of the data to identify differences between patients. However, the XPS findings support our hypothesis that oxidation of PP mesh in response to ROS secreted by adherent inflammatory cells occurred *in vivo* in this specific patient explant.

Discussion

In this study, we hypothesized that PP mesh oxidizes in response to ROS secreted by inflammatory cells that infiltrate the mesh after implantation. To test our hypothesis, we investigated the oxidative degradation of three commercial MUSs using an oxidative medium that recapitulates the microenvironment between adherent macrophages and the PP surface [17].

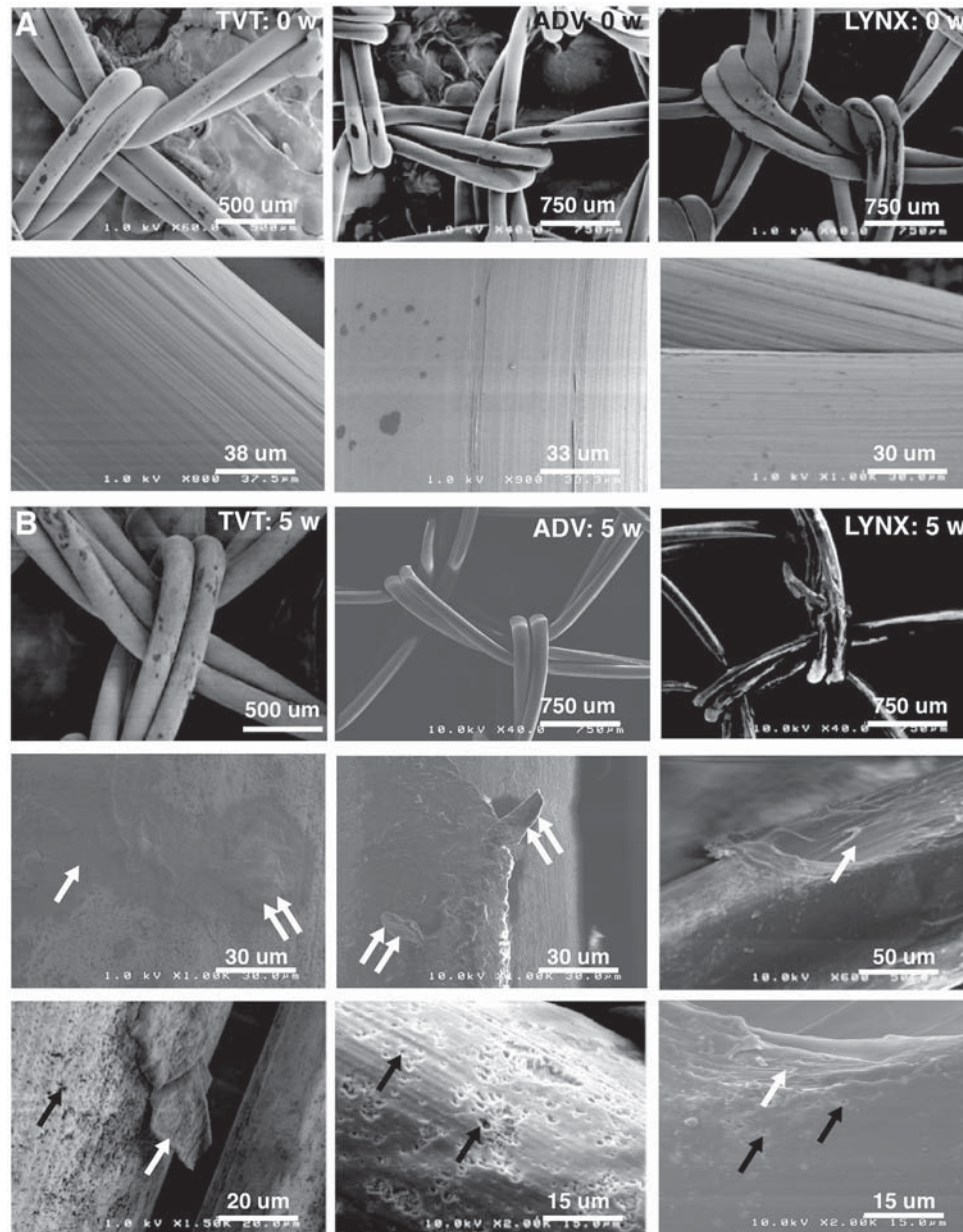


Figure 3. SEM images of PP mesh before and after incubation in oxidative medium. (A) SEM images of pristine TVT, ADV, and LYNX meshes (0 weeks incubation time). Low-magnification (40–60 \times , top row) images show the knitted monofilament structure of the meshes. Medium-magnification (800–1000 \times , bottom row) images show dark spots and longitudinal striations along the axis of extrusion as well as specks <1 μ m deep. No evidence of features associated with surface degradation was observed, such as flaking, peeling, or pitting. (B) SEM images of TVT, ADV, and LYNX meshes incubated in oxidative medium for 5 weeks. Low-magnification (40–60 \times , top row) images show the knitted monofilament structure. Medium-magnification (800–1000 \times , middle row) images revealed evidence of pits (black arrows), peeling flakes (double white arrows), and shallow craters (white arrows) on the surface. High-magnification (1500–2000 \times , bottom row) images showed small pits <5 μ m in diameter and >1 μ m deep on the surface of the mesh for all regions examined. Some regions of the mesh showed evidence of larger scale features, such as detachment of peeling flakes >10 μ m long (double white arrows) from the surface, resulting in the formation of shallow craters >10 μ m long (white arrows).

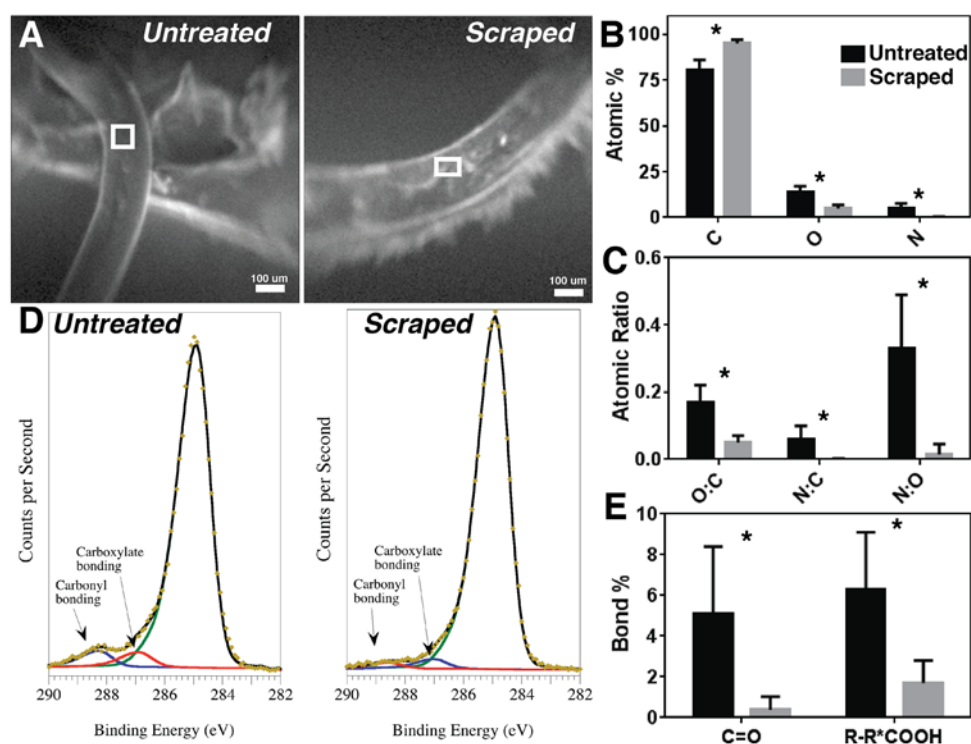


Figure 4. *In vivo* oxidation of explanted PP mesh fibers assessed by XPS. Five explanted Untreated and five Scraped fibers were analysed by XPS to assess the surface concentration of carbon, oxygen, and nitrogen atoms and C1s bonding configurations. One-way ANOVA with Tukey's HSC test for pairwise interactions showed no significant differences between residue-free and residue-present Areas of Interest (AOI) on Untreated fibers, so only Untreated residue-free fibers are shown. Both residue-free and residue-present AOIs on Untreated fibers were significantly different from Scraped fibers. (A) X-ray induced SEM showing the AOI analyzed for a representative sample. (B) Average atomic-% of C, O, and N for the AOI analyzed for each fiber. (C) Average O:C, N:C, and N:O ratios measured for each AOI. (D) High-resolution C1s spectra from Untreated and Scraped fibers. (E) Percent of C1s bonding configurations present on Untreated and Scraped fibers. The complete set of XPS data are shown in the Supplemental Data.

Note: *Denotes statistical significance ($p < 0.05$).

We observed significant increases in carbonyl and hydroxyl peak areas for each mesh after 5 weeks' incubation time in oxidative media by FTIR spectroscopy. In contrast to pristine mesh, which showed longitudinal striations and specks resulting from the extrusion process, SEM images of PP mesh samples at 5 weeks revealed evidence of large-scale pitting, flaking, and peeling associated with surface degradation. Analysis of fibers recovered from an explanted PP mesh by XPS also showed evidence of oxidation *in vivo*. These observations suggest that antioxidants added to PP mesh to protect it during processing and long-term storage do not prevent eventual oxidation in response to ROS, such as hydroxyl radicals present in the oxidative medium (Figure 1), which recapitulates the *in vivo* microenvironment. Thus, antioxidants do not protect the mesh against *in vivo* oxidation and degradation indefinitely.

PP is highly susceptible to oxidation due to its chemical structure, and the mechanism of PP oxidation at elevated temperatures *in vitro* has been known since the 1960s [3,16,25].

However, the effectiveness of antioxidants designed to protect PP against thermal oxidation [25,26] has not been systematically investigated under *in vivo* conditions. Considering recent studies reporting that the body's response to TVM is pro-inflammatory and persists for many years after implantation [8–10,21], the effects of ROS secreted by adherent inflammatory cells on PP should be considered in the design of TVM implants. We investigated oxidation of TVM using a synthetic medium known to recapitulate the oxidative microenvironment between an adherent macrophage and the biomaterial surface [17,18]. This approach enables the investigation of oxidation of PP fibers without the potentially confounding effects of protein adsorption that occurs *in vivo*. Thus, the significant increase in carbonyl and hydroxyl peaks at week 5 (Figure 2) can be explained by oxidation of the PP resulting from the reaction with hydroxyl radicals (Figure 1). Recent attempts to explain the presence of carbonyl peaks on the surface of explanted PP fibers as a crosslinked protein-formalin complex [27], biofilms [28], or residual antioxidants [27] cannot account for the increase in carbonyl and hydroperoxide groups observed after *in vitro* incubation in oxidative medium in the absence of proteins.

Our *in vitro* findings are consistent with previous studies reporting that PP oxidizes *in vivo* [9,12,13,29,30]. In an early study, stabilized PP fibers were solvent-extracted to remove the antioxidant. Extracted PP fibers (which contained a trace of residual antioxidants) and stabilized PP fibers were implanted subcutaneously in hamsters. Extracted PP fibers showed significant oxidation at 108 days, but stabilized PP fibers did not [13]. Thus, the question of whether stabilized PP can oxidize *in vivo* remained unanswered due to insufficient study duration (5 months). In a later study, Prolene® (Ethicon) monofilament PP sutures were implanted in a canine thoracoabdominal bypass model for up to 2 years [30]. Carbonyl absorbance of explanted PP sutures measured by FTIR peaked within 1–3 months post-implantation and subsequently decreased to steady-state values for 2 years.

A more recent study examining TVM explanted from 11 patients reported oxidation of PP fibers as evidenced by carbonyl peaks in the FTIR spectrum [12]. Oxidized PP was distinguished from adsorbed proteins using SEM-EDS to identify regions of PP fibers containing oxygen but not nitrogen. Similarly, we characterized the surface of PP fibers recovered from a mesh explanted from a single patient by XPS, a technique that provides quantitative analysis of the atoms and chemical bonds present at the surface. Collagen has atomic ratios N:C = 0.33 and N:O = 0.83 [31], which are 2–5-fold larger than those measured by XPS for Untreated fibers (Figure 4(C)). After scraping, the N:C and N:O ratios significantly decreased. Furthermore, nitrogen was observed on only 1 of the 5 Scraped fibers, while oxygen was observed on all Scraped fibers. Taken together, these observations suggest that both oxidized PP and adsorbed proteins are present on the surface of the Untreated fibers, which is consistent with previous studies reporting that cleaning explanted PP mesh reduces the carbonyl and hydroxyl peak areas [9,27]. Thus, the presence of oxygen (and absence of nitrogen) detected on the surface of explanted PP fibers by SEM-EDS [12] and XPS (Figure 4) cannot be attributed to protein adsorption [27] alone. Both our findings and those from the SEM-EDS analysis of explanted mesh from 11 patients [12] show that oxidation of PP mesh occurs *in vivo*. Additional studies with larger numbers of patients are warranted to investigate how PP oxidation correlates with mesh degradation and complications in humans.

The methods by which explanted samples are prepared for FTIR and XPS analysis can impact the findings. In the present study, fibers were manually dissected to remove adherent

tissue from an explanted mesh that had not been previously fixed in formalin. Other studies have utilized cleaning solutions, including bleach (sodium hypochlorite) [12,32] or enzymatic [30] treatment to remove biological material from explanted PP fibers fixed in formalin. Cleaning explanted biomedical devices with bleach is recommended in ISO 12,891 for removal of biological tissue from ultra-high molecular weight polyethylene, which has a similar chemical composition to PP [12]. Bleach and enzymatic treatment, as well as microscopic dissection, offer the advantage of selectively removing the tissue without disturbing the integrity of the brittle surface layer. A recent study has proposed a new method for cleaning explanted PP pelvic mesh using twelve cycles of bleach, enzymatic, and ultrasonic treatment, which completely removed the brittle surface layer [27]. Explanted PP fibers cleaned using this method showed no evidence of oxygen, prompting the authors to conclude that the PP fibers were not oxidized and that surface layer comprised crosslinked protein alone. However, ultrasonication cannot selectively separate oxidized PP and adsorbed protein, and thus it is likely that the aggressive twelve-cycle cleaning procedure completely removed the mixed layer of adsorbed proteins and oxidized PP. Testing the composition of the cleaning solutions after ultrasonication for oxidized PP is necessary to support the conclusion that the surface layer contains only protein. In the present study, mechanical scraping of PP fibers from a single explant that was not previously fixed in formalin removed adherent tissue without disturbing the underlying layer of oxidized PP. Further studies with larger numbers of specimens are warranted to confirm the utility of this mechanical scraping without formalin fixation cleaning procedure in additional patients.

Implantation of TVM has been associated with chronic inflammation characterized by predominantly M1 macrophages [8–10,21], PP oxidation [9,12,30], and PP degradation [9,10,12,33]. These findings point to an oxidative degradation mechanism comprising the following steps: (1) attachment of inflammatory cells to the PP surface, (2) secretion of ROS near the PP surface, (3) oxidation and embrittlement of PP, and (4) transverse cracking of PP fibers [12]. Using an established *in vitro* assay, we have shown that ROS secreted by adherent inflammatory cells can oxidize PP mesh stabilized by conventional antioxidants. Consistent with the well-known effect of thermal oxidation on PP degradation [3,16], our data highlight the contribution of ROS-mediated PP oxidation to embrittlement and surface degradation. Clinical studies correlating chronic inflammation with PP degradation [9,10] and mesh exposure [8] establish a potential link between oxidative degradation and mesh complications in patients.

The combination of a biomaterial that undergoes oxidative degradation, an oxidative microenvironment (i.e. the adherent macrophage-biomaterial interface), and residual mechanical stress can result in environmental stress cracking (ESC) [17]. As an example, transverse cracks in explanted poly(ether urethane) catheter leads have been attributed to ESC [17,20,22,34], which has been reproduced *in vitro* by treating pre-strained test specimens in oxidative medium [17]. Previous studies have reported transverse cracks in the surface of explanted PP sutures and mesh [9,29,30]. While PP is generally considered resistant to ESC, the embrittlement of PP by oxidative or other chemical degradation is described as corrosion stress cracking (CSC) [35]. Thus, when PP is exposed to strong oxidizing agents (e.g. ROS) and mechanical stress, it can undergo CSC, resulting in acceleration of the degradation process [25,35]. In the present study, we observed oxidation and surface degradation *in vitro* but did not reproduce the transverse cracking observed for explanted PP sutures and mesh *in vivo*, since the samples were not pre-strained [17] prior to incubation

in the oxidative medium. Thus, future studies in which mesh specimens are pre-strained using forces comparable to those applied *in vivo* (5–15 N [36,37]) prior to treatment with oxidative medium are warranted in order to reproduce cracking of PP mesh *in vitro*.

Conclusions

Oxidative degradation of PP pelvic mesh was evidenced by chemical and physical changes under simulated *in vivo* conditions. PP has been known to be highly susceptible to thermal oxidation at elevated temperatures *ex vivo* since the 1960s [3], and cellular mechanisms of oxidation have been suggested since the 1970s [13,38], but the present study is the first to confirm an ROS-mediated mechanism of PP oxidation and degradation. Since most commercial sources of PP use the same types of antioxidants [25], our findings suggest that oxidation would be expected during the lifetime of the device, and thus antioxidants cannot protect the device from degradation indefinitely. These findings underscore the need for further research into the relative contribution of oxidative degradation to complications associated with PP-based POP and SUI devices.

Disclosure statement

Anne D. Talley and Bridget R. Rogers have no conflicts to disclose. Russell F. Dunn is the Owner of Polymer and Chemical Technologies, which sponsored the work. He has also provided opinions for medico-legal cases on matters related to polypropylene mesh. Vladimir Iakovlev and Scott A. Guelcher have provided opinions for medico-legal cases on matters related to polypropylene mesh.

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Supplemental Data

Supplemental Materials and Methods

Fibers from an explanted polypropylene (PP) mid-urethral sling (MUS) not previously fixed in formalin were received Dr. Vladimir Iakovlev at St. Mary's Hospital (Toronto, Ontario, Canada). Fibers were supplied in numbered and sealed micro centrifuge tubes. A total of ten fibers were analyzed. Five fibers (numbered 5, 8, 23, 24, and 31) had been mechanically scraped by Dr. Iakovlev to remove tissue from the fiber surface. Another five fibers (numbered 3, 9, 11, 14, and 17) had not been scraped. Two areas were analyzed on the untreated fibers: (1) a region that appeared residue-free, and (2) a region that showed residual material. Fibers that had been cleaned were visually free of residual material, and therefore only one region of interest was examined on these fibers. Due to the small size of the fibers, no more than two independent regions could be reliably analyzed.

XPS analyses were performed in a PHI Versaprobe using Al $K\alpha$ x-rays (1486 eV). A 20- μ m diameter x-ray spot was rastered across the analysis area, and a take-off angle of 45 degrees off sample normal was used. Pass energies of 187.7 eV and 23.5 eV were used for the low- and high resolution acquisitions, respectively. Charge neutralization was accomplished using 1.1 eV electrons and 10 eV Ar⁺ ions. The energy scales of the high-resolution spectra were calibrated to place -CH₂- bonding in the carbon 1s spectrum at 284.8 eV. Relative atomic concentrations were calculated using peak areas and handbook sensitivity factors. Resulting concentrations have high precision, and therefore can be used to qualitatively compare samples collected under similar conditions.

Supplemental Results

Images of fibers. Supplemental Figure 1 shows an x-ray induced secondary electron micrograph showing the area analyzed on each sample. The area indicated on the Untreated samples is that of the residue-free area. The Scraped fibers were rougher than the Untreated fibers. Therefore, the XPS analysis volume on scraped fibers included material from deeper into the fiber

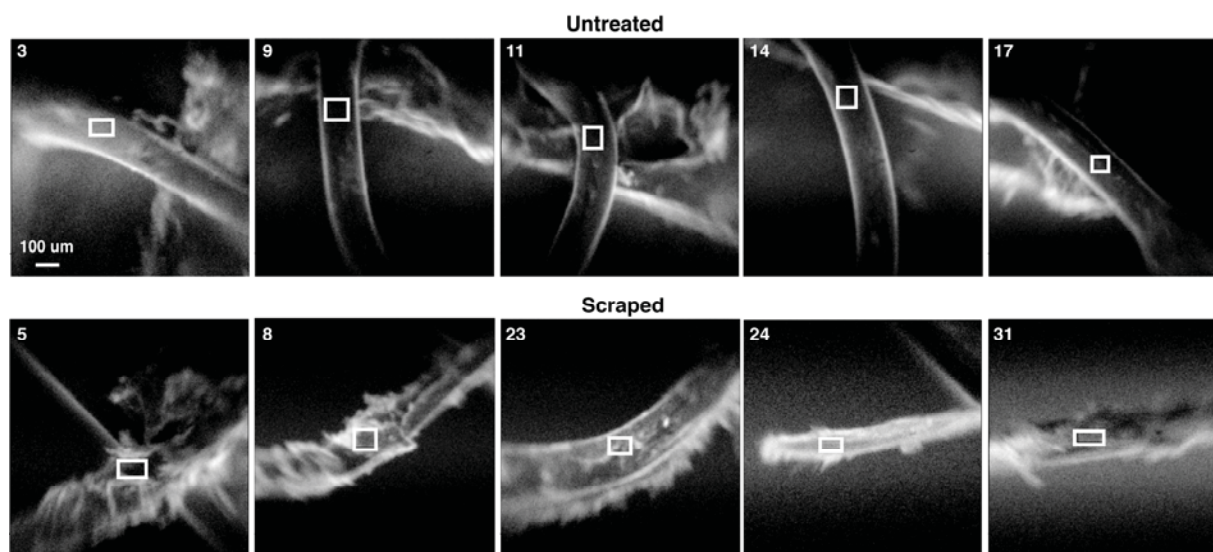


Figure S1. X-ray-induced secondary electron micrographs of the area analyzed on each fiber.

compared to fibers that had not been scraped. X-ray induced secondary electron micrographs images are not as well-defined as those obtained in an SEM because the primary x-ray beam is much larger than the electron beam used in an SEM. However, the imaging capability of this instrument enables us to define analysis areas which contain only the material of interest, which facilitates accurate interpretation of the acquired data.

Survey spectra and surface composition. A survey spectrum was collected from each fiber analyzed. Carbon, oxygen, nitrogen, and silicon were present to different degrees on all samples. Fiber number 5, which had been scraped, also contained a small amount of chlorine. Tables I and II summarize the elemental compositions determined for the Untreated and Scraped fibers, respectively. A one-way ANOVA testing the effects of surface treatment on surface chemistry found no significant ($\alpha < 0.05$) difference in atomic percents, atomic ratios, or C1s binding

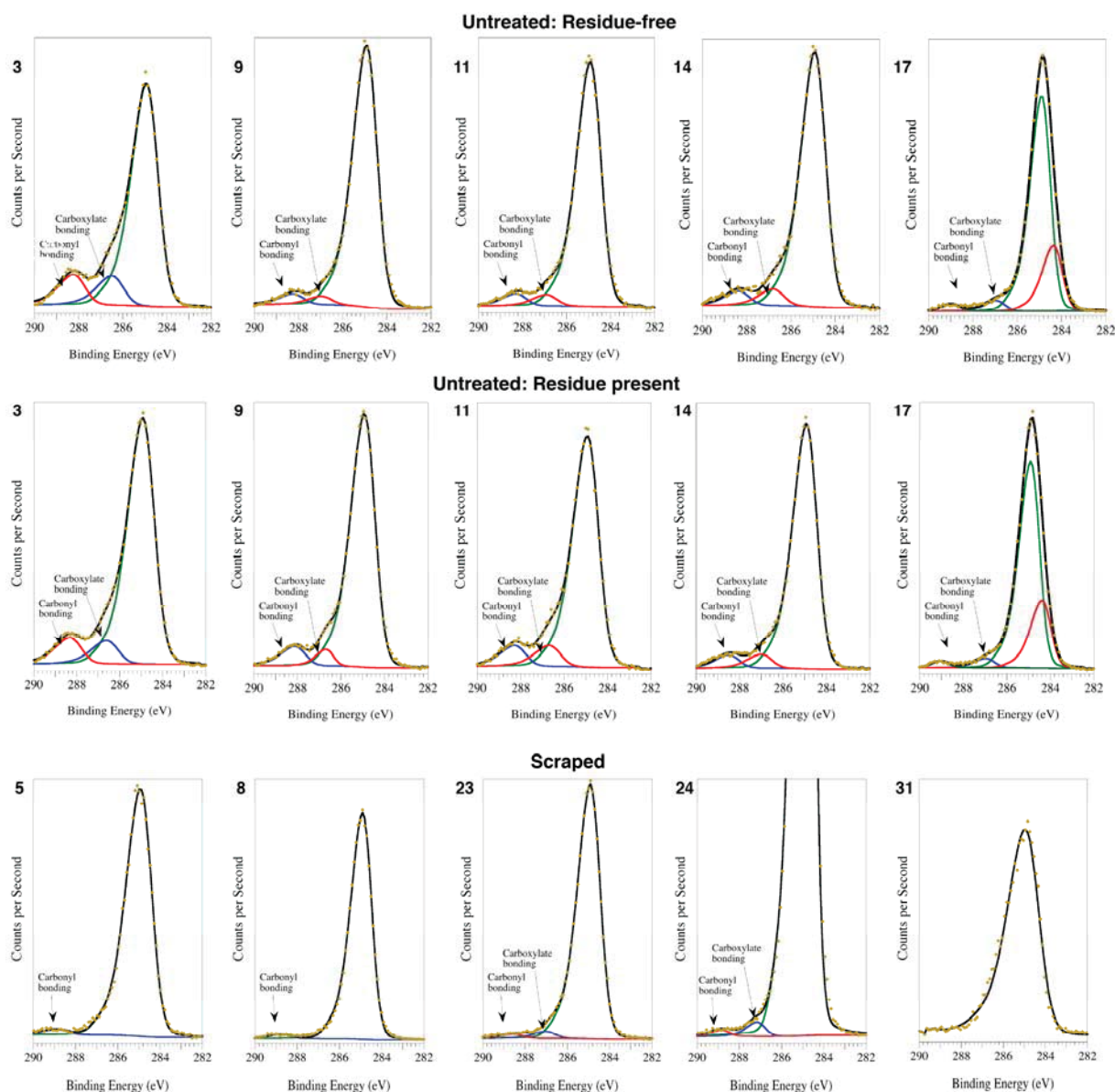


Figure S2. Survey spectra for the area analyzed on each fiber.

between residue-free and residue-present areas on the Untreated fibers. However, scraping resulted in significant differences in atomic percents, atomic ratios, and C1s bonding (Figure 4 of the manuscript). Figure S2 shows the high-resolution carbon 1s spectrum from Untreated (residue-free), Untreated (residue present), and Scraped fibers. The atomic% of carbon (C), oxygen (O), nitrogen (N), silica (Si), and chlorine (Cl) are listed in Tables S1-3.

Table S1. Summary of atomic composition of Untreated fibers (residue-free areas).

Fiber #	Atomic %				
	C	O	N	Si	Cl
3	72.7	17.7	9.5	0	0
9	84.3	11.1	4.6	0	0
11	78.3	14.4	4.2	3.0	0
14	78.2	15.7	4.3	1.7	0
17	87.4	9.7	1.1	1.8	0
Mean \pm SD	80.2 \pm 5.8	13.7 \pm 3.3	4.7 \pm 3.0	1.3 \pm 1.3	0 \pm 0

Table S2. Summary of atomic composition of Untreated fibers (areas with residue).

Fiber #	Atomic %				
	C	O	N	Si	Cl
3	77.5	14.2	8.3	0	0
9	81.5	13.1	5.4	0	0
11	74.9	17.3	5.4	2.4	0
14	82.9	12.6	3.9	0.6	0
17	87.7	10.3	0.0	2.0	0
Mean \pm SD	80.9 \pm 4.9	13.5 \pm 2.6	4.6 \pm 3.0	1.0 \pm 1.1	0 \pm 0

Table S3. Summary of atomic composition of Scraped fibers.

Fiber #	Atomic %				
	C	O	N	Si	Cl
5	93.9	6.9	0.0	0	0.2
8	93.5	5.9	0.0	0.6	0
23	93.1	5.5	0.4	1.0	0
24	97.4	2.4	0.0	0.2	0
31	96.6	3.4	0.0	0.0	0
Mean \pm SD	94.9 \pm 2.0	4.8 \pm 1.9	0.1 \pm 0.2	0.4 \pm 0.4	0.1 \pm 0.1

Analysis of carbon bonding. Spectra were curve-fitted to extract the contributions of different carbon bonding configurations present in the analysis area. All fibers that were not scraped exhibited some fraction of the carbon present bonded in carbonyl and carboxylate configurations. Two Scraped fibers (numbers 5 and 8) showed some carbonyl type bonding, while Scraped fibers numbered 23 and 24 contain both carbonyl and carboxylate type bonding. Figure S2 includes a spectrum of fiber 24 with an expanded y-axis to highlight the carbonyl and

carboxylate contributions to the carbon spectrum. The C1s spectrum from Scraped fiber number 31 shows no carbonyl nor carboxylate type bonding on this sample. Tables S4 – S6 summarize the percent of C1s bonding configurations present on each Untreated (residue-free and residue-present) and Scraped fibers, respectively.

Table S4. Summary of relative amounts (%) of the various C 1s bonding configurations present on the residue-free areas of Untreated fibers.

Fiber #	≈288 eV C=O	≈287 eV R-C*COOH	≈284.8 eV -CH	≈284.3 eV
3	10.6	10.3	78.9	ND
9	3.7	7.9	93.2	ND
11	4.5	4.2	91.3	ND
14	5.0	5.8	89.2	ND
17	1.9	3.5	72.6	21.9
Mean ± SD	5.1 ± 3.3	6.3 ± 2.8	85.0 ± 8.9	4.4 ± 9.8

Table S5. Summary of relative amounts (%) of the various C 1s bonding configurations present on the residue-present areas of Untreated fibers.

Fiber #	≈288 eV C=O	≈287 eV R-C*COOH	≈284.8 eV -CH	≈284.3 eV
3	8.9	6.9	83.2	ND
9	6.9	3.0	88.9	ND
11	7.6	7.7	84.7	ND
14	4.8	5.2	90.0	ND
17	1.8	3.2	71.6	23.5
Mean ± SD	6.0 ± 2.8	5.2 ± 2.1	83.7 ± 7.3	4.7 ± 10.5

Table S6. Summary of relative amounts (%) of the various C 1s bonding configurations present on Scraped fibers.

Fiber #	≈288 eV C=O	≈287 eV R-C*COOH	≈284.8 eV -CH	≈284.3 eV
5	ND	2.5	97.5	ND
8	ND	2.3	97.7	0.6
23	1.5	2.6	95.9	1.0
24	0.4	1.2	98.4	0.2
31	ND	ND	100	0.0
Mean ± SD	0.4 ± 0.6	1.7 ± 1.1	0.1 ± 0.2	97.9 ± 1.5

EXHIBIT D

Scott A. Guelcher, Ph.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC
REPAIR SYSTEM PRODUCTS LIABILITY
LITIGATION,

Plaintiff,

v.

THIS DOCUMENT RELATES TO CASE:
WAVE 5 CASES,

Defendant.

MASTER FILE 2:12-MD-02327
MDL 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

DEPOSITION OF SCOTT A. GUELCHER, PH.D.

AUGUST 17, 2017

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Deposition of SCOTT A. GUELCHER, PH.D. held at
Butler Snow, LLP, 150 3rd Avenue South, Suite 1600,
Nashville, Tennessee, commencing at 8:30 a.m., on the above
date, before Gina Hawkins, Tennessee Licensed Court
Reporter.

Scott A. Guelcher, Ph.D.

Page 2	Page 4
<p>1 INDEX</p> <p>2 WITNESS PAGE</p> <p>3 SCOTT A. GUELCHER, PH.D.</p> <p>4 Examination by Mr. Thomas 4</p> <p>5</p> <p>6 EXHIBITS</p> <p>7 Number</p> <p>8 1 Article entitled "Oxidation and 4</p> <p>9 degradation of polypropylene transvaginal</p> <p>10 mesh"</p> <p>11 2 Document entitled "Supplemental Data, 5</p> <p>12 Supplemental Materials and Methods"</p> <p>13 3 Expert Report of Scott Guelcher, Ph.D. 52</p> <p>14 4 Published Conference Proceedings 68</p> <p>15 5 Second Amended Notice of Deposition 86</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 SCOTT A. GUELCHER, PH.D.</p> <p>2 after having been first duly sworn, was examined and</p> <p>3 testified as follows:</p> <p>4 EXAMINATION</p> <p>5 BY MR. THOMAS:</p> <p>6 Q Good morning, Dr. Guelcher.</p> <p>7 A Good morning.</p> <p>8 (Exhibit 1 was marked for identification.)</p> <p>9 BY MR. THOMAS:</p> <p>10 Q Dr. Guelcher, I'm going to hand you Deposition</p> <p>11 Exhibit Number 1. This is a paper from the Journal of</p> <p>12 Biomaterials Science, Polymer Edition, 2017 titled</p> <p>13 "Oxidation and degradation of polypropylene transvaginal</p> <p>14 mesh."</p> <p>15 You're familiar with that document, aren't you?</p> <p>16 A Yes.</p> <p>17 Q You're one of the authors on this paper?</p> <p>18 A Yes.</p> <p>19 Q And in fact, you're the corresponding author?</p> <p>20 A Yes.</p> <p>21 Q What does it mean to be a corresponding author?</p> <p>22 A That means that I handle all the correspondence</p> <p>23 with the editor, editorial office.</p> <p>24 Q And do you handle any questions that people might</p> <p>25 have about the content of the study for readers?</p>
Page 3	Page 5
<p>1 APPEARANCES</p> <p>2 (Appearing on behalf of the Plaintiff)</p> <p>3 TIMOTHY E. JACKSON, ESQUIRE</p> <p>4 Wexler Wallace, LLP</p> <p>5 55 West Monroe Street</p> <p>6 Suite 3300</p> <p>7 Chicago, Illinois 60603</p> <p>8 tej@wexlerwallce.com</p> <p>9</p> <p>10 (Appearing on behalf of the Defendant)</p> <p>11</p> <p>12 DAVID B. THOMAS, ESQUIRE</p> <p>13 Thomas, Combs & Spann, PLLC</p> <p>14 300 Summers Street</p> <p>15 Charleston, West Virginia 25301</p> <p>16 dthomas@tcspllc.co</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 A Well, yeah, all the authors together respond to</p> <p>2 comments from reviewers, and then I send the final response</p> <p>3 to the journal.</p> <p>4 Q Okay. You're the point person for any issues</p> <p>5 that might arise around the article?</p> <p>6 A That's right.</p> <p>7 (Exhibit 2 was marked for identification.)</p> <p>8 BY MR. THOMAS:</p> <p>9 Q Let me show you Deposition Exhibit Number 2. And</p> <p>10 Deposition Exhibit Number 2 is titled "Supplemental Data,</p> <p>11 Supplemental Materials and Methods."</p> <p>12 Do you recognize this document?</p> <p>13 A Yes.</p> <p>14 Q And is this the supplemental data that's</p> <p>15 referenced on the first page of Exhibit Number 1 down at the</p> <p>16 bottom?</p> <p>17 A Yes, I believe so.</p> <p>18 Q And this is the data -- Exhibit Number 2 is the</p> <p>19 data that Exhibit Number 1 refers to for the tables and</p> <p>20 figures contained in that Exhibit Number 1; is that correct?</p> <p>21 A Yeah. There's a citation to the supplemental</p> <p>22 data in the paper.</p> <p>23 Q Was the supplemental data made available at the</p> <p>24 same time as the original study?</p> <p>25 A What do you mean by "made available"?</p>

2 (Pages 2 to 5)

Scott A. Guelcher, Ph.D.

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<p>1 Q At the time that you published Exhibit Number 1, 2 was Exhibit Number available? 3 MR. JACKSON: Objection to form. 4 A I didn't check that, but that's usually the 5 standard practice in the papers published. It's typically 6 published with the supplemental data at the time. 7 BY MR. THOMAS: 8 Q That was -- I'm sorry. I didn't mean to 9 interrupt you. 10 That was your intent at the time to have the 11 Exhibit Number 1 and Exhibit No. Number 2 available to the 12 reader at the same time? 13 A Yeah, but that's the editorial office. I mean, 14 you know, I submit the documents to the editor at the same 15 time, and then the Journal makes it available online. So I 16 can't control that. 17 That's the way it's typically done, but what I 18 control is what I submit to the editorial office. 19 Q Okay. Who is Anne Talley? 20 A She was my former graduate student. 21 Q And what contribution did Anne Talley make to 22 this Exhibit Number 1? 23 A I believe that she -- let's see if I addressed 24 that in the paper. I don't remember if I did or not. 25 Q I don't believe that you did, but take your time.</p>	<p>1 A He assisted with writing the manuscript. 2 Q I'll note that Dr. Dunn, Russell Dunn, who's also 3 an author, his company is noted as a sponsor of the study. 4 What other contribution did Russell Dunn have in 5 Exhibits 1 and 2? 6 MR. JACKSON: Object to form of the last 7 question. 8 A So Dr. Dunn, his company, as you said, funded the 9 study. He performed the experiments. I should be more 10 specific. 11 The FTIR and the SEM measurements were performed 12 by Dr. Dunn and people that were being supported by the 13 grant, I believe. He would know more of the details, but I 14 would say that he did the FTIR and SEM experiments. 15 BY MR. THOMAS: 16 Q And what contribution did you have to Exhibit 17 Number 1? 18 A So I wrote the first draft of the paper. I 19 compiled all the data from my collaborators, my student. I 20 prepared some of the figures, I think, and I did most of the 21 writing. 22 Q Who owns the FTIR equipment that was used in the 23 study? 24 A I don't -- I don't know. Russell Dunn would know 25 the details of that. I don't know who owns that equipment.</p>
Page 7	Page 9
<p>1 A Yeah, so Anne, I think, did the analysis of the 2 FTIR data to calculate the peak areas. I believe she did 3 some of that work. 4 It's hard to remember exactly what else. She 5 contributed to the writing, probably some of the methods, 6 but it's hard to say, you know, exactly who wrote what. I 7 would say she contributed to writing and analysis of the 8 FTIR data. 9 Q And what is her area of expertise? 10 A Well, biomaterials. She works for FDA now, so 11 has expertise in biomaterials. 12 Q And who is Bridget Rogers? 13 A So Bridget Rogers is an associate professor in my 14 Department of Chemical Engineering at Vanderbilt. 15 Q And what contribution did Ms. Rogers make to this 16 Exhibit Number 1? 17 A So her area of expertise is in films, XPS. So 18 her contribution was, she did the XPS experiments, she 19 analyzed the data. She largely wrote a lot of the parts of 20 the paper on XPS. That's her area of expertise. 21 Q And in the report I note that Dr. Iakovlev, who's 22 also an author, contributed the AMS explant and also cleaned 23 the AMS explant. 24 Did Dr. Iakovlev make any other contribution to 25 Exhibits 1 or 2?</p>	<p>1 Q Same answer for the scanning electron microscope 2 and XPS? 3 A No. The SEM is a Vanderbilt resource, and so is 4 the XPS. 5 Q Who was the person responsible for discussing 6 with Vanderbilt the use of the XPS and SEM equipment for 7 purposes of Exhibit Number 1 and 2? 8 A Well, that would be Dr. Dunn. 9 Q Did you have any involvement in that? 10 A Any involvement in what specifically? 11 Q In any negotiations or discussions with 12 Vanderbilt about the use of the XPS and SEM for the work 13 that's reflected in Exhibits 1 and 2. 14 A No, I don't believe so. That was Dr. Dunn's 15 responsibility. 16 Q Did you have any control over the disbursement of 17 funds that were provided by Russell Dunn's group for this 18 study? 19 MR. JACKSON: Objection to form. 20 A No, I didn't. 21 BY MR. THOMAS: 22 Q Do you know whether Vanderbilt was compensated 23 for the use of their XPS and SEM equipment? 24 A So the SEM is a core resource at Vanderbilt. 25 What that means is, you pay a user fee to use it. And when</p>

3 (Pages 6 to 9)

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<p style="text-align: right;">Page 10</p> <p>1 it says -- so in the acknowledgments we say that this work</p> <p>2 was supported by Polymer Chemical Technologies. Polymer</p> <p>3 Chemical Technologies paid the user fee for that SEM.</p> <p>4 I don't remember how the XPS was handled. For</p> <p>5 the SEM it's a core resource, so the University was paid</p> <p>6 through that billing agreement.</p> <p>7 Q What do you mean by "core resource"?</p> <p>8 A So large pieces of equipment like SEM are -- it's</p> <p>9 not possible for individual professors to own things like</p> <p>10 this because they're so expensive to maintain, but many</p> <p>11 people want to use it. So we have large equipment like SEM</p> <p>12 that isn't a core. In this case it's the Institute for</p> <p>13 Nanoscale -- Nanoscience and Engineering. And in order to</p> <p>14 recover the costs of using the equipment, that core charges</p> <p>15 an hourly rate, and then that rate has to be paid. In this</p> <p>16 case it was paid by PCT.</p> <p>17 So it's a facility that's owned by the</p> <p>18 University, and anybody can access it by paying the user</p> <p>19 fee. It's an hourly fee.</p> <p>20 Q And did I understand you to say you do not know</p> <p>21 how the University was compensated for use of XPS equipment?</p> <p>22 A I do not. That would be -- so the XPS is owned</p> <p>23 by the University. Dr. Rogers is the one who coordinates</p> <p>24 the use of the XPS.</p> <p>25 There have been some changes to how that is</p>	<p style="text-align: right;">Page 12</p> <p>1 that polypropylene would oxidize under stimulated in-vivo</p> <p>2 conditions.</p> <p>3 Q What does this study tell us about any oxidation</p> <p>4 under in-vivo conditions?</p> <p>5 A Well, we used a test solution. I believe that's</p> <p>6 addressed on page 3, the last paragraph in the introduction.</p> <p>7 We used an oxidized media that comprised 20 percent hydrogen</p> <p>8 peroxide and the cobalt chloride, which causes this reaction</p> <p>9 to form hydroxyl radicals, which are a form of reactive</p> <p>10 oxygen species that's present in-vivo, so we were simulating</p> <p>11 that -- those oxidative conditions.</p> <p>12 That paper has been known for some time and cited</p> <p>13 a number of times. So that was the -- that was the</p> <p>14 approach.</p> <p>15 Q You also it tested an AMS explant; correct?</p> <p>16 A That's right.</p> <p>17 Q And for what purpose did you test the AMS</p> <p>18 explant?</p> <p>19 A I hope it's okay, what I'd like to do is read --</p> <p>20 discuss right from the paper what I said because it's been a</p> <p>21 while. I don't -- I'm just taking a little time, if that's</p> <p>22 okay.</p> <p>23 Q Sure. Let me ask you this question: Did you</p> <p>24 review Exhibits 1 and 2 prior to your deposition?</p> <p>25 A I did, but I didn't have a lot of time. This</p>
<p style="text-align: right;">Page 11</p> <p>1 managed, and I just don't remember what was in place at that</p> <p>2 time.</p> <p>3 Q At the time that you used the University's</p> <p>4 equipment, are you required to disclose the purpose for</p> <p>5 which you're using it?</p> <p>6 A No. It's -- you just pay the user's fee. I</p> <p>7 mean, you would have to disclose it if it's potentially --</p> <p>8 you know, if it's a concern about safety, but this is a</p> <p>9 pretty standard analysis. So typically that's not done.</p> <p>10 Q Did you -- did you or any of the other authors,</p> <p>11 to your knowledge, disclose to the University that you were</p> <p>12 using their XPS and SEM machines for this specific study?</p> <p>13 A No, there would be no reason for that.</p> <p>14 Q Okay.</p> <p>15 A That was handled through the -- Dr. Dunn had</p> <p>16 his -- PCT had a contractual relationship with the</p> <p>17 University, and so once that relationship is established,</p> <p>18 you're free to use the resources like you would for</p> <p>19 another --</p> <p>20 Q Doctor, what was the purpose of Exhibit Number 1?</p> <p>21 What were you trying to set out to do?</p> <p>22 A I believe we addressed that in the abstract. So</p> <p>23 in the study we hypothesized that polypropylene oxidizes</p> <p>24 under in-vitro conditions simulating the foreign body</p> <p>25 reaction so that the purpose was to test that hypothesis</p>	<p style="text-align: right;">Page 13</p> <p>1 just came about pretty fast, and I published this awhile</p> <p>2 ago.</p> <p>3 So I've reviewed these documents. I just want to</p> <p>4 be careful. So I believe that you asked me what's the</p> <p>5 purpose of the -- why did we test the explanted fiber?</p> <p>6 That's what you asked?</p> <p>7 Q That's right.</p> <p>8 A I can't find what I'm looking for right now, but</p> <p>9 basically we were testing the hypothesis that this oxidation</p> <p>10 could also happen in-vivo. That was the question we were</p> <p>11 asking is, can fiber also be oxidized in-vivo in the body.</p> <p>12 Q And you obtained this AMX -- sorry.</p> <p>13 Doctor, you obtained this AMS implant from Dr.</p> <p>14 Iakovlev?</p> <p>15 A That's right.</p> <p>16 Q Do you know what kind of implant it was?</p> <p>17 A We had some discussion about this. I can tell</p> <p>18 you if it's in the -- because of patient confidentiality, we</p> <p>19 were limited in what we knew, but I can tell you what we did</p> <p>20 know.</p> <p>21 So all we know is that it was an AMS midurethral</p> <p>22 sling. We don't know the product. We just know that it was</p> <p>23 a sling.</p> <p>24 Q Do you know how long it was in the patient?</p> <p>25 A We do not.</p>

4 (Pages 10 to 13)

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<p style="text-align: right;">Page 14</p> <p>1 Q Do you know the reasons the midurethral sling was 2 removed?</p> <p>3 A Well, it was explanted for complications other 4 than mucosal erosion. This is what we know from the 5 records.</p> <p>6 Q Is that all that you know?</p> <p>7 A Yeah. We put in the paper what we knew about the 8 explant.</p> <p>9 Q I'm sorry if I asked this already. My head is a 10 little fuzzy, too.</p> <p>11 Doctor, do you know how long the AMS implant was 12 in the patient before it was removed?</p> <p>13 A Yeah, I said unfortunately we don't. This is all 14 we could get from the patient records is that it was 15 explanted for some complication other than erosion.</p> <p>16 Q Doctor -- sorry. You finished?</p> <p>17 A Yes.</p> <p>18 Q Doctor, the paper reports that Dr. Iakovlev 19 cleaned this AMS explant; correct?</p> <p>20 A That's right. He did that work.</p> <p>21 Q Did he do that at his laboratory in Toronto?</p> <p>22 A He did.</p> <p>23 Q Did he record his methodology in removing the 24 tissue, as he's explained in the report?</p> <p>25 A So we explained -- he does a microscopic</p>	<p style="text-align: right;">Page 16</p> <p>1 Rogers performed the XPS. Dr. Dunn did the FTIR and SEM. 2 So they would have that experimental data. I don't have it. 3 I didn't do the work.</p> <p>4 Q Have you reviewed any of the experimental data, 5 written experimental data upon which Drs. Dunn, Iakovlev, 6 Talley and Rogers relied to generate the data that's in 7 Exhibits 1 and 2?</p> <p>8 A Yeah, I've reviewed the raw data with them as we 9 were writing the paper, but I don't have it. I mean, as we 10 were preparing the figures and writing the manuscript, I 11 reviewed the data with them.</p> <p>12 Q Did you have it in electronic form or hard copy?</p> <p>13 A I don't remember. I think -- I don't remember. 14 Usually what I do with my students is, I get the figures, 15 and then in some cases I'll put the figures together into 16 panels, but I don't -- we don't -- I don't necessarily keep 17 the raw data on the studies on my computer. We store that 18 elsewhere. I mean, I don't --</p> <p>19 Q Where did you store the raw data that was used to 20 generate Exhibits Number 1 and 2?</p> <p>21 A Again, that would be Dr. Dunn's data. I didn't 22 do it.</p> <p>23 Q Dr. Guelcher, I'm not trying to be difficult. 24 You testified that you reviewed the raw data generated by 25 these folks as you did their work with them.</p>
<p style="text-align: right;">Page 15</p> <p>1 dissection where he can remove pieces of tissue using some 2 small tweezers under a microscope, and a scalpel blade he 3 used as well.</p> <p>4 So he developed this technique, and I believe 5 he's been using it for some time.</p> <p>6 Q Have you seen a written protocol for the cleaning 7 of the mesh that's described in Exhibits 1 and 2?</p> <p>8 A I don't remember. I don't know that I've seen a 9 written protocol. I mean, the level of detail that we 10 provided in the paper is consistent with what, you know, you 11 typically would do in a paper.</p> <p>12 I haven't seen -- I don't know if he has a 13 detailed protocol. I just know that he's done this for some 14 time.</p> <p>15 Q Do you know whether he has any notes or records 16 of the procedure he followed to clean the AMS explant?</p> <p>17 A I don't know the answer to that either.</p> <p>18 Q Do you know if he has any photographs that he 19 took during the cleaning procedure?</p> <p>20 A Again, I suspect that he does, but I haven't seen 21 them. He would be able to provide that information.</p> <p>22 Q As a part of this study, was it your practice to 23 keep laboratory notebooks of the work that you performed?</p> <p>24 A Again, Dr. Dunn did all of that. So, again, just 25 to make it clear, Dr. Iakovlev prepared the fibers. Dr.</p>	<p style="text-align: right;">Page 17</p> <p>1 A Yeah.</p> <p>2 Q At some point you had access to that data. What 3 did you do with the data that you reviewed with your 4 co-authors as they generated the data that goes into 5 Exhibits 1 and 2?</p> <p>6 MR. JACKSON: I think that's asked and answered 7 at this point.</p> <p>8 A I don't remember the details. This was awhile 9 ago. But, for example, you would run an FTIR spectrum on 10 the FTIR machine, and those data would be stored in that 11 computer, and then we would pull them up and look at the 12 data.</p> <p>13 And then the final disposition of those data, I 14 don't know if Dr. Dunn left it on that computer or moved it 15 off and stored it somewhere else. I don't know. It's not 16 my data.</p> <p>17 BY MR. THOMAS:</p> <p>18 Q Is it fair to understand that as you sit here 19 today, you don't have access to any of the raw data 20 underlying Exhibits Number 1 and 2?</p> <p>21 A What do you mean by "access"?</p> <p>22 Q Could you get it if you wanted it?</p> <p>23 A Yeah. I would go to Dr. Dunn and get the data.</p> <p>24 Q And you would expect Dr. Dunn to have all of the 25 data that underlies Exhibits Number 1 and 2?</p>

5 (Pages 14 to 17)

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<p>1 A That would be my -- I mean, when you do</p> <p>2 collaborative scientific research projects like this, each</p> <p>3 investigator controls his or her -- it's just the way -- the</p> <p>4 collegial way to do it. Each investigator controls his or</p> <p>5 her raw data, is responsible for storing that under some</p> <p>6 kind of long-term conditions, but we do so many runs on the</p> <p>7 instrument, it's not typical to leave all the data there.</p> <p>8 At some point somebody takes it off and stores it somewhere,</p> <p>9 but I don't typically do that.</p> <p>10 Q I understand. I'm just trying to figure out</p> <p>11 where it might be.</p> <p>12 A Well, Dr. Dunn would have it. I mean --</p> <p>13 Q Would he have -- are you finished?</p> <p>14 A Yeah.</p> <p>15 Q Would Dr. Dunn, as far as you're concerned as the</p> <p>16 corresponding author, have control of the data from Talley,</p> <p>17 Rogers, Iakovlev and Dunn?</p> <p>18 A I want to be really clear because I feel like</p> <p>19 there's some confusion. I may take a little bit of time to</p> <p>20 answer.</p> <p>21 Q Sure.</p> <p>22 A So just to make it clear, Dr. Dunn did the FTIR</p> <p>23 and the SEM, or people that worked for Dr. Dunn. I don't</p> <p>24 know the details of his arrangement. He's the PI for that</p> <p>25 part of the work, principal investigator for that part of</p>	<p>1 way -- this was a research project. I want to make it</p> <p>2 really clear. This was not testing for litigation. This</p> <p>3 was a research project.</p> <p>4 Q Doctor, is it fair to understand you didn't ask</p> <p>5 Dr. Dunn or any of the other co-authors for their data in</p> <p>6 order to prepare for this deposition?</p> <p>7 A I did not because I didn't think it was</p> <p>8 appropriate.</p> <p>9 Q All right. Let's go to Exhibit Number 1, please,</p> <p>10 and go to page 7.</p> <p>11 By the way, in preparation for your deposition,</p> <p>12 have you read the expert reports of Dr. Thames and</p> <p>13 Dr. McLean?</p> <p>14 A I've read them in the past several months. I</p> <p>15 didn't have time to go through them again last night, but I</p> <p>16 have read them in the past several months, I'd say.</p> <p>17 Q Have you read their criticisms of this -- what</p> <p>18 I'll call the Talley paper?</p> <p>19 A I have, but I don't remember exactly what those</p> <p>20 were.</p> <p>21 Q When you read the criticisms of the Talley paper,</p> <p>22 did you go back to investigate those criticisms?</p> <p>23 MR. JACKSON: Objection, form.</p> <p>24 A Investigate? I don't remember. I mean, I don't</p> <p>25 know how appropriate it is to talk about other litigation</p>
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<p>1 the work. For the FTIR and the SEM, he would have those raw</p> <p>2 data.</p> <p>3 Now, my student didn't do those measurements.</p> <p>4 She did the analysis. But again, everything was given</p> <p>5 back -- Dr. Dunn would have all of that. The XPS was done</p> <p>6 by Dr. Rogers, so she would have -- any additional data on</p> <p>7 the XPS Dr. Rogers would have.</p> <p>8 And then the only thing that Dr. Iakovlev would</p> <p>9 have would be protocols and pictures, et cetera, of how he</p> <p>10 prepared the fibers. He would have that.</p> <p>11 So if you wanted all that, you'd have to go to</p> <p>12 them to get it because it's their work. It's not my work.</p> <p>13 I worked with them to write the paper. I concede to the</p> <p>14 hypothesis and took the lead on writing the paper, but I</p> <p>15 relied on my colleagues to provide the raw data. So that's</p> <p>16 why I don't have it.</p> <p>17 It is -- I don't want to give the impression that</p> <p>18 it's not accessible. It's just under the control of my</p> <p>19 colleagues who prepared it.</p> <p>20 Q But to be clear, if you wanted access to the</p> <p>21 data, you could request it of them, and they would give it</p> <p>22 to you?</p> <p>23 A I'm not comfortable doing that because it's not</p> <p>24 my work, and it's a legal proceeding. I think it would have</p> <p>25 to go through them, not through me. That's just a collegial</p>	<p>1 other than this but, you know, I am working on other cases,</p> <p>2 and in the context of that I read their comments, and I made</p> <p>3 some replies in some reports. But I don't -- I just -- it</p> <p>4 would help me if you had me look at something. I'm going on</p> <p>5 my memory. It's just a little tough.</p> <p>6 Q All I can ask you to do, Doctor.</p> <p>7 When you say you made some replies in some</p> <p>8 reports, are those expert witness replies?</p> <p>9 A Yes. It's not public.</p> <p>10 Q Are these the ones you submitted in Australia?</p> <p>11 A Yeah, I believe that I did, but I just can't</p> <p>12 remember -- I have read it, and I have thought about it, and</p> <p>13 I thought that I responded to it, but I just can't remember</p> <p>14 the details.</p> <p>15 Oh, well, maybe one thing I can remember is</p> <p>16 that -- well, you know what? I'm going from my memory, so I</p> <p>17 just want to be -- I just can't remember details right now.</p> <p>18 Q Sure. What's your best recollection?</p> <p>19 A I just can't -- I can't remember right now what I</p> <p>20 wrote.</p> <p>21 Q Okay. Are you on page 7 of your report?</p> <p>22 A Yeah.</p> <p>23 MR. JACKSON: When you say "report," do you mean</p> <p>24 the article?</p> <p>25</p>

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<p>1 BY MR. THOMAS:</p> <p>2 Q I need to start over because I got the wrong</p> <p>3 page. Would you go to Exhibit 1, please, and page 10.</p> <p>4 A Oh, okay.</p> <p>5 Q Page 10 has a Figure 4 that has four categories</p> <p>6 of images marked A through E. What's the purpose of</p> <p>7 Figure 4?</p> <p>8 A Would you like me to talk through the message in</p> <p>9 Figure 4? Is that what you're asking me?</p> <p>10 Q That's right.</p> <p>11 A So in Panel A -- and again, this is Dr. Rogers'</p> <p>12 experiments. But in Panel A, these are SEM images of the</p> <p>13 explanted fibers from the AMS mesh, and she focused on</p> <p>14 what's called an area of interest, which is that white box.</p> <p>15 And that area of interest is exposed to X-rays, and then in</p> <p>16 response you get photoelectrons that you can basically use</p> <p>17 to determine the composition of what -- of that surface in</p> <p>18 that small box.</p> <p>19 Q What does it mean for untreated and scraped?</p> <p>20 A That's defined in the paper. Let me give you a</p> <p>21 precise definition.</p> <p>22 So the untreated, basically -- it wasn't scraped.</p> <p>23 We just -- Dr. Iakovlev literally -- my understanding was,</p> <p>24 he explanted the fibers from the mesh under the microscope,</p> <p>25 and he didn't do the dissection. And then the scrape -- he</p>	<p>1 don't see any nitrogen. So that would suggest there's no</p> <p>2 protein.</p> <p>3 Q What's the atomic percentage figure on the -- I</p> <p>4 guess that's the -- on that axis?</p> <p>5 A Well, that's the percentage of each atom that's</p> <p>6 in the spectra. So it's 80 percent carbon, 15 percent --</p> <p>7 it's the percentage of each atom.</p> <p>8 Q Do you expect, do all these add up to</p> <p>9 100 percent?</p> <p>10 MR. JACKSON: Objection, form.</p> <p>11 A I think so, but the raw data are in the</p> <p>12 supplement.</p> <p>13 BY MR. THOMAS:</p> <p>14 Q I'll get to that in just a minute.</p> <p>15 A You know, it's the percentage of the total of</p> <p>16 everything that comes off the surface.</p> <p>17 Q Okay. What is Panel C?</p> <p>18 A So in Panel C we calculated the ratios of each of</p> <p>19 those atoms. So its oxygen to carbon -- so Panel C is</p> <p>20 basically calculated from Panel B. That would be oxygen to</p> <p>21 carbon, nitrogen to carbon and nitrogen to oxygen ratios.</p> <p>22 Q Why do you do that?</p> <p>23 A Well, the purpose here was to see, again, the</p> <p>24 nitrogen to carbon and nitrogen to oxygen ratios go way down</p> <p>25 after scraping, which basically the same point here is to</p>
Page 23	Page 25
<p>1 did the microscopic dissection. So that would be the</p> <p>2 difference between the two groups.</p> <p>3 Q Okay.</p> <p>4 A So what's shown in Panel D, those are the --</p> <p>5 those are the peaks that come off, and there's a</p> <p>6 mathematical analysis that Dr. Rogers did for those peaks to</p> <p>7 actually come up with what's shown in Panels B, C and E.</p> <p>8 Sorry, did you --</p> <p>9 Q Just to make it clear, Panel D is the XPS</p> <p>10 testing?</p> <p>11 A Yeah. So Panel D is the emission spectra. So in</p> <p>12 Panel D you're looking at the energy of those photoelectrons</p> <p>13 that come off the surface, and so you get these</p> <p>14 distributions. And then those raw data are analyzed to</p> <p>15 prepare the plots in Panels B, C and E.</p> <p>16 Q What is the data that's represented in Panel B?</p> <p>17 A So the emissions spectra tell us something about</p> <p>18 both the specific atoms that are on the surface as well as</p> <p>19 the binding states. So in Panel B, this is, we show,</p> <p>20 carbon, oxygen and nitrogen. And the point in Panel B is</p> <p>21 that the untreated fibers had nitrogen and oxygen, as you</p> <p>22 would expect, because these weren't treated, right, so there</p> <p>23 were -- again, the purpose of the scraping that Dr. Iakovlev</p> <p>24 did was to remove the protein, right, and so you would see</p> <p>25 oxygen and nitrogen on the surface, but after scraping we</p>	<p>1 show that your scraping is removing the proteins, but</p> <p>2 there's still oxygen on the surface. So the only</p> <p>3 explanation for that would be oxidation. That's the</p> <p>4 message.</p> <p>5 Q Just to nail this down, is there any purpose</p> <p>6 other than to show the effect of the scraping for Panels B</p> <p>7 and C?</p> <p>8 A Well, it's not quite that black and white. I</p> <p>9 mean, I think -- the purpose of doing the scrape and the</p> <p>10 untreated is to show that, you know, before cleaning there's</p> <p>11 protein on the surface, and then after cleaning the protein</p> <p>12 is almost completely removed. There's very little nitrogen.</p> <p>13 In a lot of samples we didn't see any nitrogen, but there's</p> <p>14 still oxygen. And so the question then is, where does that</p> <p>15 oxygen come from? And what we believe is, it's coming from</p> <p>16 oxidation because there's no nitrogen on the surface, which</p> <p>17 would imply there's no protein.</p> <p>18 So that's why we did both was to look at the</p> <p>19 change, you know, to try to be rigorous about it. That's</p> <p>20 why we did both.</p> <p>21 Q What's the purpose of Panel E?</p> <p>22 A So Panel E shows the bonding configurations.</p> <p>23 Q What is a bonding configuration?</p> <p>24 A So if we look at mechanism of degradation of</p> <p>25 polypropylene. You would expect carbonyl groups, which is</p>

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<p style="text-align: right;">Page 26</p> <p>1 the C over on the left. That's the carbonyl.</p> <p>2 And then the other binding configuration is what</p> <p>3 Dr. Rogers would call carboxylate, and this is similar to</p> <p>4 the hydroperoxide degradation product.</p> <p>5 So the point here is to show that before and</p> <p>6 after scraping we see both of those. Again -- and this is a</p> <p>7 point that, you know, Dr. Thames has made in his work about</p> <p>8 the protein. Proteins have carbonyl and carboxylate bonds.</p> <p>9 So if you have protein on the surface, you would expect to</p> <p>10 see quite a bit of bonding, which we do. But even after</p> <p>11 that protein has been removed manually, and then you don't</p> <p>12 see any nitrogen, you still see these carboxylate and</p> <p>13 carbonyl groups. That's the purpose. So it's further</p> <p>14 supporting what we saw in Panels B and C. We see the types</p> <p>15 of bonds that you would see for oxidized polypropylene even</p> <p>16 after the protein has been removed.</p> <p>17 Q What's the significance of the carbonyl numbers</p> <p>18 standing alone?</p> <p>19 MR. JACKSON: Objection, form.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q Or do you have to look at them side by side in</p> <p>22 order to make --</p> <p>23 A Oh, no -- well, how do I answer that? I'm going</p> <p>24 to try to answer your question. If you don't like it, try</p> <p>25 again. I won't be offended. I'm trying to deal with this</p>	<p style="text-align: right;">Page 28</p> <p>1 that it's oxidized. I think having the untreated groups</p> <p>2 strengthens the rigor of that conclusion. That's the way I</p> <p>3 would answer your question.</p> <p>4 So I do think it stands alone, but I like the way</p> <p>5 I present it in the paper where we do both.</p> <p>6 Q What is the takeaway from Panel E?</p> <p>7 A Panel E. Well, the takeaway would be that after</p> <p>8 you remove the protein, you still see carbonyl and</p> <p>9 carboxylate bonds that are consistent with the degradation</p> <p>10 products of oxidized polypropylene.</p> <p>11 Q Let's go to page 4 of Exhibit 2. Keep that page</p> <p>12 open. You're going to need it.</p> <p>13 A Okay. Page 4, okay.</p> <p>14 Q Do you have that in front of you?</p> <p>15 A Yes.</p> <p>16 Q Do you see Table S6?</p> <p>17 A Yes.</p> <p>18 Q Table S6, page 4, Exhibit 2, is titled "Summary</p> <p>19 of relative amounts (percentage) of the various C 1S bonding</p> <p>20 configurations present on scraped fibers."</p> <p>21 A That's right.</p> <p>22 Q And that is the basis for the scraped fibers</p> <p>23 figure in Figure E on page 10 of Exhibit 1; correct?</p> <p>24 A That's correct.</p> <p>25 Q And S6 is where Ms. Rogers has recorded the data</p>
<p style="text-align: right;">Page 27</p> <p>1 in a rigorously scientific way.</p> <p>2 Q Maybe I can help you a little bit.</p> <p>3 MR. JACKSON: He was going to answer the</p> <p>4 question.</p> <p>5 BY MR. THOMAS:</p> <p>6 Q Fine. I'm just trying to make it easier on him.</p> <p>7 Go ahead.</p> <p>8 A The reason we did both groups is because I think</p> <p>9 it's scientifically more rigorous to look at the change.</p> <p>10 So you could just -- you could just clean the</p> <p>11 fiber and see carbonyl and carboxylate on the surface and</p> <p>12 conclude that it oxidized, but I think it's more rigorous to</p> <p>13 look at the untreated fiber as well, where you would expect</p> <p>14 to see a lot of carbonyl and a lot of carboxylate, which we</p> <p>15 do. Okay, there's protein on the surface. When I remove</p> <p>16 what I believe to be protein, those bonds come down, which I</p> <p>17 would expect, but they're still there.</p> <p>18 So I think it's -- I prefer to really talk about</p> <p>19 it like it is in the paper, discussing it in its totality.</p> <p>20 And the reason we did those controls was to really give a</p> <p>21 good rigorous analysis and scientific perspective on what we</p> <p>22 did.</p> <p>23 So I would say if I look at -- I know it's a long</p> <p>24 answer. But the fact that I see carbonyl on a scraped fiber</p> <p>25 would tell me -- this shows no nitrogen -- I would conclude</p>	<p style="text-align: right;">Page 29</p> <p>1 that she collected from her XPS; correct?</p> <p>2 A Yes.</p> <p>3 Q And if you looked at Table 6 on page 4 of Exhibit</p> <p>4 Number 2 where it says, 288 eV, that's the XPS column for</p> <p>5 carbonyl group; correct?</p> <p>6 A Yes.</p> <p>7 Q And of the five measurements she took, three were</p> <p>8 nondetect; correct?</p> <p>9 A That's right.</p> <p>10 Q And then she recorded measurements for fibers 23</p> <p>11 and 24. At the bottom is a column for mean plus or minus</p> <p>12 SD. What does that mean?</p> <p>13 A That's the mean plus or minus the standard</p> <p>14 deviation of those five numbers.</p> <p>15 Q What's the purpose for including that column in</p> <p>16 this kind of table?</p> <p>17 A You mean the row?</p> <p>18 Q Yes, the row. I'm sorry.</p> <p>19 A Well, we calculate the average in the standard</p> <p>20 deviation so we can compare the different groups. We can</p> <p>21 quantitatively compare the groups.</p> <p>22 Q From an analytical perspective, what's the</p> <p>23 meaning of the mean plus or minus the standard deviation for</p> <p>24 the carbonyl group, which is .4 plus or minus .6?</p> <p>25 A Well, that would be the standard deviation of the</p>

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<p style="text-align: right;">Page 30</p> <p>1 measurement. It's to measure the spread of the distribution</p> <p>2 of the data.</p> <p>3 Q And so .4 is the mean --</p> <p>4 A Yes.</p> <p>5 Q -- of the values; correct?</p> <p>6 A That's right.</p> <p>7 Q And .6 is the standard deviation or the error</p> <p>8 rate; correct?</p> <p>9 A I don't know if I'd call it error. It's the</p> <p>10 distribution of the samples.</p> <p>11 So we have -- like you pointed out, there were</p> <p>12 three of them that basically were zero. We couldn't see</p> <p>13 anything. It's probably not zero, but practically speaking,</p> <p>14 it's zero. We couldn't measure it. So for two of them we</p> <p>15 measured it. We averaged them together to give -- that's</p> <p>16 what we did.</p> <p>17 So there's a distribution of measurements.</p> <p>18 That's what's reflected by the standard deviation.</p> <p>19 Q What does it mean when the measurement is .4 plus</p> <p>20 or minus .6? What does it mean to you as a chemist looking</p> <p>21 at this data?</p> <p>22 A It's the spread of the distribution.</p> <p>23 Q Does it tell anything to you about the validity</p> <p>24 of the data?</p> <p>25 A What do you mean "the validity of the data"?</p>	<p style="text-align: right;">Page 32</p> <p>1 spread of the distribution.</p> <p>2 I explain in the paper how we did that. I mean,</p> <p>3 it's just a measure of the spread of the distribution. I'm</p> <p>4 not really sure what you're asking.</p> <p>5 Q Can you answer the question?</p> <p>6 A I'm trying to, but I'm not really sure what</p> <p>7 you're asking me.</p> <p>8 Q In reporting compiled data like you have here,</p> <p>9 when you subject it to the mean versus the standard</p> <p>10 deviation, don't you want to have the mean to be greater</p> <p>11 than the standard deviation in order to have reportable</p> <p>12 data?</p> <p>13 MR. JACKSON: Objection, form.</p> <p>14 A But that doesn't -- no, I don't agree with what</p> <p>15 you're saying. I mean, that's a calculation of the data to</p> <p>16 enable comparisons between groups. The data stands as it</p> <p>17 is, you know. I said there's three of them we did not</p> <p>18 detect carboxylate. Two of them we did. From that</p> <p>19 distribution, we can calculate mean and the standard</p> <p>20 deviation, but we -- it doesn't detract from the data. The</p> <p>21 data are the data. They're distributed as they are.</p> <p>22 This is just a means for modeling the data or</p> <p>23 explaining it. It doesn't detract from the data.</p> <p>24 Q Why didn't you report, in Exhibit Number 1, the</p> <p>25 fact that the mean was less than the standard deviation?</p>
<p style="text-align: right;">Page 31</p> <p>1 Q The accuracy of the data as reported.</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A I mean, the data that are reported. There are</p> <p>4 five measurements for the amount of carbonyl on each of the</p> <p>5 fibers. That's what reported. This is a statistical</p> <p>6 calculation.</p> <p>7 The data are reported as they are, and some --</p> <p>8 I'm going to say zero, even though, just to make it easier.</p> <p>9 It's not zero. It's some number that was so small we</p> <p>10 couldn't measure it, but we'll call it zero.</p> <p>11 Three of them we didn't see the carboxylate, and</p> <p>12 two of them we did. So what that tells me is that those</p> <p>13 regions, those very small regions that were probed, after</p> <p>14 removing the protein, what we thought was the protein, it</p> <p>15 could have removed some of the oxidized polypropylene.</p> <p>16 Maybe that particular region didn't see much oxidation. We</p> <p>17 don't know, but we couldn't measure oxidation. We didn't</p> <p>18 see it. When I say we couldn't measure it, we didn't</p> <p>19 measure the presence of the carbonyl on those three regions.</p> <p>20 That's what it means.</p> <p>21 BY MR. THOMAS:</p> <p>22 Q Doctor, in statistical analysis, in order to have</p> <p>23 reportable data, don't you want the mean to be greater than</p> <p>24 the standard deviation?</p> <p>25 A I mean, standard deviation, it's a measure of the</p>	<p style="text-align: right;">Page 33</p> <p>1 A I mean, I wouldn't normally report that. I mean,</p> <p>2 we did the -- we tested -- we compared the groups using</p> <p>3 different tests, and we plotted it. We showed the standard</p> <p>4 deviation. It's just a means of characterizing the</p> <p>5 distribution.</p> <p>6 I mean, if you have a distribution centered at</p> <p>7 zero, then the means is going to be zero, and the</p> <p>8 distribution is going to be -- it's an analysis technique.</p> <p>9 It's not -- you can't control how the data distributed, how</p> <p>10 it is distributed.</p> <p>11 Q But the meaning of the data is impacted by the</p> <p>12 mean compared to the standard deviation; correct?</p> <p>13 A Well, the statistical testing is -- no, no. When</p> <p>14 I did the -- I'd have to go back and look at exactly what I</p> <p>15 did.</p> <p>16 We compared distributions. This is just written</p> <p>17 here as a means for the reader to, you know, get some kind</p> <p>18 of understanding of how the data are distributed, but it</p> <p>19 doesn't impact it. The data are the data.</p> <p>20 Q Next column on Table S6, again, which was used</p> <p>21 for Table E in Exhibit 1; correct?</p> <p>22 A You know, Figure 4E, that's what you mean, right?</p> <p>23 Q Correct.</p> <p>24 A Yeah, okay.</p> <p>25 Q It says, "287 eV, RC COOH." What does that</p>

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<p>1 represent?</p> <p>2 A Well, it's just the nature of that carboxylate</p> <p>3 bond.</p> <p>4 My understanding -- again, this is Dr. Rogers'</p> <p>5 work. But, you know, my understanding is, you can basically</p> <p>6 see that it's -- 287 electron volts is consistent with</p> <p>7 carboxylate type of bonding where you have a COOH -- and it</p> <p>8 doesn't tell you the actual details of the bond, but you</p> <p>9 know that you have that kind of configuration where you have</p> <p>10 carbon bonded to oxygen bonded to oxygen bonded to hydrogen.</p> <p>11 There could be several different types of bonding</p> <p>12 configurations, but it has this general structure.</p> <p>13 So it's just too difficult to, you know, say</p> <p>14 exactly what the bonding configuration is, but it's some</p> <p>15 form of this.</p> <p>16 Q Okay. Now, Doctor, if you look at S6 under the</p> <p>17 carboxylate bond column, they record values for fibers 5 and</p> <p>18 8; correct?</p> <p>19 A 5 and 8, yeah. 2.5 and 2.3, is that what you</p> <p>20 mean?</p> <p>21 Q That's correct. If you go to page 2 of Exhibit 2</p> <p>22 --</p> <p>23 A Yeah.</p> <p>24 Q Go to page 2 of Exhibit 2.</p> <p>25 A Okay.</p>	<p>1 Dr. Rogers did that work. She would be the one to answer</p> <p>2 details about that.</p> <p>3 It's not -- I agree that it's not labeled in the</p> <p>4 diagram.</p> <p>5 Q And you can't see a peak that resembles 2.5 in a</p> <p>6 carboxylate area, can you?</p> <p>7 MR. JACKSON: Objection, asked and answered.</p> <p>8 A Yeah, I mean, I think I answered it. You know,</p> <p>9 it's very small. I'd have to look at her analysis of how</p> <p>10 she did that.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q Okay. The same question for fiber 8 in Table S6.</p> <p>13 It shows a carboxylate peak of 2.3?</p> <p>14 A Yes.</p> <p>15 Q If you look at fiber 8 in Figure S2 on page 2 of</p> <p>16 Exhibit 2, there's no carboxylate peak of 2.3 appearing in</p> <p>17 that image as well?</p> <p>18 A Same answer for number 5. I mean, again, she</p> <p>19 didn't label it. I'd have to look at her analysis to figure</p> <p>20 out what she did there.</p> <p>21 Q Did you -- did you prepare Figure E -- Figure 4E</p> <p>22 on page 10 of Exhibit 1?</p> <p>23 A I think so. I know I prepared Figure 4. I don't</p> <p>24 know. I can't remember if I did it or if Anne did it.</p> <p>25 Q Would you agree with me that Figure 4E includes</p>
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<p>1 Q Do you have that?</p> <p>2 A Yeah.</p> <p>3 Q And page 2 of Exhibit 2 shows the XPS images on</p> <p>4 which the author relied to generate the figures that are</p> <p>5 contained in Table S6; correct?</p> <p>6 A Yes.</p> <p>7 Q And under scraped fiber, Figure S2, there are</p> <p>8 images for Figures 5 and 8; correct?</p> <p>9 A Yes.</p> <p>10 Q And on S6 on page 4 for fiber 5, it shows a</p> <p>11 carboxylate bond value of 2.5. Do you see that?</p> <p>12 A Yeah.</p> <p>13 Q If you look at fiber 5 on page 2, there is no</p> <p>14 carboxylate peak of 2.5. Do you agree with that?</p> <p>15 A I don't know. She didn't label it. She</p> <p>16 prepared -- Dr. Rogers prepared these figures. I don't know</p> <p>17 that I would say it's not there. Just, it's not labeled.</p> <p>18 Q Do you see anything that resembles a carboxylate</p> <p>19 peak of 2.5 on Figure 5?</p> <p>20 A I can't tell by looking at this resolution. I'm</p> <p>21 having a hard time seeing it.</p> <p>22 Q You can't see it?</p> <p>23 A Yeah, again, it's not my data. You know, Dr.</p> <p>24 Rogers did this analysis. There's an analysis that's done</p> <p>25 of these data that you have to deconvolute the peaks, and</p>	<p>1 the values 2.5 for fiber 5 and 2.3 for fiber 8 in the bar</p> <p>2 chart for the carboxylates?</p> <p>3 MR. JACKSON: Objection to form.</p> <p>4 A Those are the numbers that are plotted in the</p> <p>5 panel.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q Okay. And do you know the statistical impact of</p> <p>8 removing those values from what you show in 4E?</p> <p>9 MR. JACKSON: Objection to form.</p> <p>10 A I haven't looked at that. I relied on Dr. Rogers</p> <p>11 for this analysis, so I'd have to go back to her and discuss</p> <p>12 this with her. We calculated -- Anne and I did this</p> <p>13 together. I can't remember who did what. We were relying</p> <p>14 on the numbers that she provided in the table.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q And the table you're referring to, Table S6?</p> <p>17 A S6, yeah. We didn't go back and -- this is</p> <p>18 her -- this is what she did. She did the analysis of the</p> <p>19 XPS. So we were relying on her analysis, so I'd have to go</p> <p>20 back to her and discuss that with her.</p> <p>21 Q Since you wrote this paper, you've become aware</p> <p>22 that both Dr. Thames and Dr. McLean have raised this</p> <p>23 criticism of this paper, haven't you?</p> <p>24 MR. JACKSON: Objection to form.</p> <p>25 A I haven't heard -- I don't remember seeing this</p>

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<p style="text-align: right;">Page 38</p> <p>1 point. They wrote some other things about it. They -- I</p> <p>2 mean, they wrote other things. I've never seen this,</p> <p>3 though.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q Since the publication --</p> <p>6 A Just to clarify, this is the first time I've been</p> <p>7 aware of this viewpoint.</p> <p>8 Q Since publication of the Talley paper, have you</p> <p>9 had discussions with -- is it Dr. Rogers?</p> <p>10 A Yes.</p> <p>11 Q -- with Dr. Rogers about the data in Table 6 as</p> <p>12 compared to the XPS on page 2 of Exhibit 2?</p> <p>13 A I haven't discussed this with her for a while,</p> <p>14 probably since we wrote the paper.</p> <p>15 Q Okay. Staying on page 4 of Exhibit 2, who</p> <p>16 prepared the tables in S4, S5 and S6?</p> <p>17 A Dr. Rogers produced these. I mean, I may have --</p> <p>18 I can't remember who did -- I may have made the table based</p> <p>19 on the numbers that she gave us, but she produced those</p> <p>20 numbers.</p> <p>21 Q Okay. Who designed the tables, for lack of a</p> <p>22 better word? Who came up with the format for the tables?</p> <p>23 A Dr. Rogers.</p> <p>24 Q Do you see the column on S4 of 284.8 eV?</p> <p>25 A Mm-hmm.</p>	<p style="text-align: right;">Page 40</p> <p>1 overlap. Like I said, there are methods that have been --</p> <p>2 that are used for this. I don't remember the details of</p> <p>3 those right now, but it's a pretty standard approach.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q Okay.</p> <p>6 A Again, with XPS, this is again Dr. Rogers' work.</p> <p>7 And I've published other papers with her on XPS, and she did</p> <p>8 the separation of the peaks.</p> <p>9 Q In Tables 4, 5 and 6, the last column is 284.3</p> <p>10 eV, and there's no description of what that area is. Do you</p> <p>11 know what that is?</p> <p>12 A So my understanding, that particular peak is</p> <p>13 often what people refer to as adventitious carbon. I think</p> <p>14 it's in the paper. Let me see if I can find it here.</p> <p>15 Q I'm not familiar with that term. What did you</p> <p>16 call it, adventitious?</p> <p>17 A I think the technical term is "adventitious."</p> <p>18 Let me see if it's discuss in here, and then I can give you</p> <p>19 a more precise answer. Maybe we didn't discuss it.</p> <p>20 Q I don't remember seeing it.</p> <p>21 A Basically, I think the best way I can answer that</p> <p>22 is, it's some form of carbon bond that we can't attribute.</p> <p>23 It's difficult to say exactly which bonding configuration it</p> <p>24 could be. So it's a carbon bond, but we don't -- like with</p> <p>25 these other bonds we can say it's carbonyl or carboxylate,</p>
<p style="text-align: right;">Page 39</p> <p>1 Q It's labeled "CH." What does CH mean?</p> <p>2 A Well, that would be the percent of carbon in that</p> <p>3 carbon hydrogen bonding configuration. So that would be</p> <p>4 like a hydrocarbon bond. CH is what percentage of the</p> <p>5 carbon is bound to the hydrogen. The carbon bond is what</p> <p>6 percentage of your hydrogen bonds, is my understanding.</p> <p>7 Q And you mentioned before the concept of</p> <p>8 deconvolution. What is that?</p> <p>9 A Well, my understanding is, you have these</p> <p>10 overlapping peaks, you know, and these are distributions of</p> <p>11 energy. So they overlap in their mathematical methods that</p> <p>12 you can use to determine, you know, which peak corresponds</p> <p>13 to which type of bond or atom. That's the type of work</p> <p>14 that -- that's what Dr. Rogers does.</p> <p>15 Q Do you consider yourself an expert in the area of</p> <p>16 deconvolution?</p> <p>17 MR. JACKSON: Objection to form.</p> <p>18 A Well, this is -- this is a method that -- I mean,</p> <p>19 I think I've used it before where you have it any kind of</p> <p>20 overlapping peaks and any kind of analysis. We can see this</p> <p>21 in GPC or HPLC or different chromatography. You can have</p> <p>22 these overlapping peaks. So you have to find a way to</p> <p>23 calculate which is which because the peaks -- I'm not</p> <p>24 explaining it very well.</p> <p>25 You have to be able to separate that region of</p>	<p style="text-align: right;">Page 41</p> <p>1 but we can't say specifically which type of carbon bond</p> <p>2 probably because of overlapping peaks. That's my</p> <p>3 understanding.</p> <p>4 So I would say that it's a carbon bond, but we</p> <p>5 can't provide the details, so we listed it just because --</p> <p>6 the numbers need to add up. We listed everything that we</p> <p>7 saw. It's some form of carbon bond that we don't know the</p> <p>8 details about. I would probably say it that way.</p> <p>9 Q Would you defer to Dr. Rogers for an answer on</p> <p>10 that?</p> <p>11 A Yeah, she could give a more -- Dr. Rogers could</p> <p>12 give a more maybe detailed answer on that. I mean, I think</p> <p>13 she would say the same thing. We just don't -- it's a</p> <p>14 limitation of the method. You can't -- you see a peak</p> <p>15 there, but ascribing that to a specific bonding</p> <p>16 configuration is challenging, so we just report the number</p> <p>17 at the peak.</p> <p>18 That's why we report it. Like you can see in the</p> <p>19 table, we don't list a bonding configuration because we</p> <p>20 don't know.</p> <p>21 Q If you look at page 1 of Exhibit 2, at page 1 of</p> <p>22 Exhibit 2 right in the middle of the page it says, "The</p> <p>23 energy scales at the high-resolution spectra were calibrated</p> <p>24 to place CH₂ bonding in the carbon 1s spectrum at 284.8 eV."</p> <p>25 Do you see that?</p>

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<p>1 A Yeah.</p> <p>2 Q And we go back now to page 4 of the same exhibit,</p> <p>3 you see 284.8 eV. It says, "CH" as opposed to "CH2." Are</p> <p>4 those the same?</p> <p>5 A I think so. I think the CH2 bonding, I think</p> <p>6 what that's referring to is a methyl group, which would be a</p> <p>7 carbon bonded to two other carbons bonded to hydrogens. So</p> <p>8 I think these are the -- I think what she's saying here is</p> <p>9 that basically the scale was calibrated so that those methyl</p> <p>10 carbons are showing up here at 284.8. I think it's</p> <p>11 consistent. That's my understanding.</p> <p>12 Q Has anybody ever told you the column that's</p> <p>13 marked "CH" should be "CH2," and the column that's left</p> <p>14 blank should be "CH"?</p> <p>15 A I've not heard that before. Yeah, I'm not --</p> <p>16 Q Do you know why that wouldn't be true?</p> <p>17 MR. JACKSON: Objection to form.</p> <p>18 BY MR. THOMAS:</p> <p>19 Q Does that sound implausible or impossible to you,</p> <p>20 as a person involved in this study or as a person with</p> <p>21 knowledge of this test?</p> <p>22 MR. JACKSON: Objection to form.</p> <p>23 A Well, I think as I answered you before, it's not</p> <p>24 consistent with my understanding of the test.</p> <p>25 My understanding is that this is a carbon</p>	<p>1 that we can't say what the exact nature of the bond is.</p> <p>2 Q If you look at Table S4, fiber 9.</p> <p>3 A Yeah.</p> <p>4 Q If you go across, those columns should add up to</p> <p>5 about 100; right?</p> <p>6 MR. JACKSON: Objection to form.</p> <p>7 A I think they should, yeah.</p> <p>8 BY MR. THOMAS:</p> <p>9 Q If you add them up, they add up to 104.8. Do you</p> <p>10 have any explanation for that?</p> <p>11 A No. I'd have to look at that.</p> <p>12 Q Would you defer to Dr. Rogers for her explanation</p> <p>13 of that, or could you answer that question?</p> <p>14 A I would have to talk to her to find out whether,</p> <p>15 you know, that was in what she gave me or whether, when I</p> <p>16 typed the table out in the supplement. I don't know. I'd</p> <p>17 have to check. I'd have to go back and talk to her. I</p> <p>18 couldn't answer that right now.</p> <p>19 Q Let's go back to page 2 of Exhibit 2. Page 2 of</p> <p>20 Exhibit 2 are the XPS -- do you call them spectra or images?</p> <p>21 What do you call them?</p> <p>22 A Spectra.</p> <p>23 Q -- spectra that Dr. Rogers took. You mentioned</p> <p>24 the concept of deconvolution.</p> <p>25 Do you see any deconvolution in any of the images</p>
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<p>1 hydrogen bond and this is some form of carbon bonding</p> <p>2 configuration that we can't -- I mean, if we could ascribe</p> <p>3 this to a specific bonding configuration, we would have done</p> <p>4 that. That's my understanding. I'm going to look at it</p> <p>5 more. I hadn't heard that before.</p> <p>6 Q So just to be clear, the first one you mentioned</p> <p>7 is the CH, 284.8. The second one you described was the last</p> <p>8 one, which was 284.3, which is the one not labeled in the</p> <p>9 exhibit; correct?</p> <p>10 A Yeah, and I think we didn't label it because,</p> <p>11 again, we can't say with certainty what that bonding</p> <p>12 configuration is. It's an observation that we needed to</p> <p>13 report, but we did not assign a bonding configuration</p> <p>14 because we weren't confident in that. It's part of the</p> <p>15 total signal that came of the fiber, so we reported it.</p> <p>16 Q Okay. So in Figures 4 and 5, if you note, that</p> <p>17 you have four nondetects in the last unlabeled column and</p> <p>18 then values of 21.9 and 23.5.</p> <p>19 Do you have any explanation for a nondetect in 4</p> <p>20 and a value of over 20 percent for the fiber 17?</p> <p>21 A I'm confused about where you're talking about.</p> <p>22 That table? I don't, other than what I gave you, that it's,</p> <p>23 you know, it's a form a carbon bonding that's -- I would say</p> <p>24 that we don't believe it's carbon and oxygen bonding like</p> <p>25 the first two columns, but it's some form of carbon bonding</p>	<p>1 that are on page 2 of Exhibit 2?</p> <p>2 A Let me be more specific about my answer. I</p> <p>3 thought this was addressed. I can't seem to find what I'm</p> <p>4 looking for.</p> <p>5 These are -- my understanding, these are the raw</p> <p>6 data, so these are just showing the peaks. I don't think</p> <p>7 we're showing here the analysis to get those peak areas. I</p> <p>8 mean, these are just the peak -- these are the raw data, I</p> <p>9 think. She's not showing that here.</p> <p>10 Q You mentioned that she did deconvolution of the</p> <p>11 samples she tested; correct?</p> <p>12 A I need to find this because I'm relying on my</p> <p>13 memory. Wait a minute. Maybe it's in here. Okay. I think</p> <p>14 I found it. I'm going to be more specific in my answer. I</p> <p>15 don't want to necessarily use this term "deconvolution."</p> <p>16 Basically, what we say in the paper is that the</p> <p>17 curve fitting to extract the contributions of different</p> <p>18 carbon bonding configurations present in the analysis area.</p> <p>19 So she did that curve fitting. I don't believe that's shown</p> <p>20 on these spectra, but she did that analysis to come up with</p> <p>21 the numbers on the table.</p> <p>22 Q Okay.</p> <p>23 A That's what she did.</p> <p>24 Q And the analysis that she used to come up with</p> <p>25 the figures in the table are not available to us today; is</p>

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<p style="text-align: right;">Page 46</p> <p>1 that correct?</p> <p>2 A I don't -- I don't know that -- she has that. I</p> <p>3 don't have that. Dr. Rogers would have that.</p> <p>4 Q And it's not in Exhibit 2?</p> <p>5 A No. That sort of work is beyond the scope of</p> <p>6 what people would typically publish.</p> <p>7 Q So is it your best recollection that Dr. Rogers</p> <p>8 did or did not do deconvolution?</p> <p>9 A Well, like I said, I don't think I want to use</p> <p>10 that term. I want to use the term that's in the paper.</p> <p>11 I'll just be more precise that she did her fitting and</p> <p>12 mathematical analysis to resolve these, in some cases,</p> <p>13 overlapping peaks, and she did her fitting to come up with</p> <p>14 the numbers in the table. That's what she did. Exactly how</p> <p>15 she did that, I don't know.</p> <p>16 Q How is curve fitting different from</p> <p>17 deconvolution?</p> <p>18 A I don't -- it's the same idea. I mean, I was</p> <p>19 using those words interchangeably. I should be really</p> <p>20 precise in that she analyzed the spectra to come up with the</p> <p>21 numbers in the table. She produced -- for the paper we</p> <p>22 showed the spectra, and we listed the results of what she</p> <p>23 called curve-fitting analysis in the paper to come up with</p> <p>24 the numbers.</p> <p>25 The details of how she did that, we probably</p>	<p style="text-align: right;">Page 48</p> <p>1 don't remember the details of exactly how she processed</p> <p>2 those data.</p> <p>3 Q So to answer my question concisely, if you can,</p> <p>4 you defer to Dr. Rogers for the analysis that she used,</p> <p>5 whether it be curve fitting or deconvolution, to come up</p> <p>6 with the data in the tables?</p> <p>7 MR. JACKSON: Objection to form.</p> <p>8 A How do I say this? Yeah, she made those</p> <p>9 decisions. She made the decision about, here's the spectra.</p> <p>10 You can look at the spectra, and you can see there are</p> <p>11 overlapping peaks. And then the XPS field, there are</p> <p>12 various accepted methods. There are, again, mathematical</p> <p>13 approaches where you could address that issue of overlapping</p> <p>14 peaks and come up with -- I mean, she makes some comments</p> <p>15 like that she's using methods that are standard and</p> <p>16 published and known, but she did it, and I don't remember</p> <p>17 the details of what she did.</p> <p>18 Q Okay. On page 2 of Exhibit 2 --</p> <p>19 A Okay.</p> <p>20 Q -- the document says, "A survey spectrum was</p> <p>21 collected from each fiber analyzed. Carbon, oxygen,</p> <p>22 nitrogen and silicon were present on all samples."</p> <p>23 Why would silicon be present on any of these</p> <p>24 samples?</p> <p>25 A Not knowing the manufacturing history -- we</p>
<p style="text-align: right;">Page 47</p> <p>1 discussed this at some point, but I don't remember the</p> <p>2 details of how she did it.</p> <p>3 Q As you sit here today, do you know any difference</p> <p>4 that you can explain to me between curve fitting and</p> <p>5 deconvolution?</p> <p>6 A I was -- I was using those terms interchangeably.</p> <p>7 The point I was trying to make is that there are overlapping</p> <p>8 peaks in the spectra, and you have to use various</p> <p>9 mathematical methods to resolve those overlapping peaks, and</p> <p>10 that's what Dr. Rogers did. At some point I've been</p> <p>11 referring to that as "deconvolution." At other times I've</p> <p>12 been referring to it as "curve fitting." Basically what I'm</p> <p>13 saying is that there are overlapping peaks, and Dr. Rogers</p> <p>14 did the analysis to address that and come up with the</p> <p>15 numbers in the table. That's what she did.</p> <p>16 Q And for questions about the analysis that Dr.</p> <p>17 Rogers undertook to come up with the numbers in the table,</p> <p>18 you would defer to Dr. Rogers?</p> <p>19 A I would refer to her. I've done this in other --</p> <p>20 I mean, I just published another paper this year doing very</p> <p>21 similar things, using XPS to look at a surface. I did the</p> <p>22 same thing with her there. She typically does the XPS. She</p> <p>23 does the XPS experiments herself. She does the data</p> <p>24 analysis. We talk about it, she explains the limitations.</p> <p>25 She explains what she did, and then we publish it, but I</p>	<p style="text-align: right;">Page 49</p> <p>1 suspected it's something from the manufacturing process, but</p> <p>2 without knowing all of those details, it's hard to say for</p> <p>3 certain, but I would say probably typically, if you find</p> <p>4 something like that on the fiber, that it's going to be</p> <p>5 something related to the manufacturing of the fiber. That's</p> <p>6 our best guess.</p> <p>7 Q Do you know the chemical composition of the</p> <p>8 Boston Scientific meshes you analyzed?</p> <p>9 A The chemical, you mean -- the polypropylene, you</p> <p>10 mean like the formulation?</p> <p>11 Q That's right.</p> <p>12 A I can't remember it. I don't know. If it's a</p> <p>13 Boston Scientific product, I don't know how much detail I</p> <p>14 can give, but it's --</p> <p>15 Q All I want to know is, does the Boston Scientific</p> <p>16 formulation of the polypropylene mesh that you analyzed</p> <p>17 contain silicon?</p> <p>18 A Oh, I see what you're getting at. I don't know.</p> <p>19 We didn't -- that's not in the paper. I don't know.</p> <p>20 Q And you know that the TVT formulation does not</p> <p>21 contain silicon?</p> <p>22 MR. JACKSON: Objection to form.</p> <p>23 A I'm trying to remember. I don't remember the</p> <p>24 formulation off the top of my head, but I can't really say.</p> <p>25</p>

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<p style="text-align: right;">Page 50</p> <p>1 BY MR. THOMAS:</p> <p>2 Q Let me ask you to assume. We've done this</p> <p>3 before. Let me ask you to assume that the TVT formulation</p> <p>4 of polypropylene and its proline does not contain silicon.</p> <p>5 What could be the source of the silicon that appeared in</p> <p>6 your XPS spectra?</p> <p>7 MR. JACKSON: Objection, asked and answered.</p> <p>8 A Well, these are AMS fibers, so it's hard to say.</p> <p>9 I mean, I don't know. I mean, these are AMS fibers. I</p> <p>10 don't know what the formulation of AMS fiber is. We didn't</p> <p>11 look at it.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q Okay. Fiber number 5 that had been scraped</p> <p>14 contained a small amount of chlorine. Any explanation for</p> <p>15 why chlorine might be present on fiber number 5?</p> <p>16 A I would say it's probably similar to the silica</p> <p>17 case. We don't typically -- that would come from something</p> <p>18 in the manufacturing processing, but we don't know the</p> <p>19 source of the chlorine.</p> <p>20 Q Okay.</p> <p>21 A Do you want to take a break for a few minutes?</p> <p>22 Q Sure, whenever you're ready. Let's do that.</p> <p>23 (Recess was taken from 9:45 to 9:51.)</p> <p>24 BY MR. THOMAS:</p> <p>25 Q Dr. Guelcher, was there any consideration given</p>	<p style="text-align: right;">Page 52</p> <p>1 MR. JACKSON: Objection to form.</p> <p>2 A Can I go to my report on that? I don't know if</p> <p>3 that has been entered into evidence, has it?</p> <p>4 Can you ask that again?</p> <p>5 MR. THOMAS: Can you read that back? I'm not</p> <p>6 sure I can remember it that well.</p> <p>7 (Last question was read back.)</p> <p>8 MR. JACKSON: Counsel, he said he'd like to look</p> <p>9 at a copy of his report to possibly answer that</p> <p>10 question. Is that something you could provide him?</p> <p>11 BY MR. THOMAS:</p> <p>12 Q I sure can, if you think that would help him.</p> <p>13 I'm trying to save time.</p> <p>14 A I think it would. As I said, this deposition</p> <p>15 came very quickly.</p> <p>16 Q For me, too.</p> <p>17 A I reviewed the documents, but it helps to have</p> <p>18 things in front of me so I can, you know --</p> <p>19 Q Doctor, I can assure you, we're both under time</p> <p>20 constraints, and I assure you I'm trying to be as efficient</p> <p>21 as I can.</p> <p>22 A No, I understand.</p> <p>23 (Exhibit 3 was marked for identification.)</p> <p>24 BY MR. THOMAS:</p> <p>25 Q I marked as Exhibit No. 3 your copy of the Wave 5</p>
<p style="text-align: right;">Page 51</p> <p>1 to conducting an FTIR analysis of the AMS explanted mesh?</p> <p>2 A Yes, we discussed it. I can't remember if it's</p> <p>3 explained in the paper.</p> <p>4 The problem was, as these fibers were very small,</p> <p>5 and so we were pretty constrained to -- the advantage of the</p> <p>6 XPS is, you can examine those very small regions of the</p> <p>7 fiber. I think we were really just limited on sample size</p> <p>8 to do the FTIR. We just didn't have much sample. That's</p> <p>9 what I remember.</p> <p>10 Q Okay. Would FTIR have been your first choice?</p> <p>11 A No, I don't think so, because, you know -- I</p> <p>12 think this is in my report. Again, with the FTIR, it's --</p> <p>13 it has been -- you know, Clave brings it up in his paper.</p> <p>14 I've talked about it in when I wrote about Dr. Thames'</p> <p>15 study. FTIR, it's harder to be more conclusive about oxygen</p> <p>16 and nitrogen.</p> <p>17 As I explain in the report, the EDS and the XPS</p> <p>18 are more -- they can tell you about these specific atomic</p> <p>19 concentrations. By testing fibers that have been scraped</p> <p>20 and unscraped, you know, I think XPS is a more specific</p> <p>21 technique. That's why we chose that because we can actually</p> <p>22 look at the amount of nitrogen and the amount of oxygen on</p> <p>23 the surface of the fibers.</p> <p>24 Q Would FTIR of the scraped, explanted AMS mesh</p> <p>25 tell you the extent of your success in cleaning the mesh?</p>	<p style="text-align: right;">Page 53</p> <p>1 report, not the exhibits, just the text of the report.</p> <p>2 A So the question is, would FTIR be a method for --</p> <p>3 it's hard -- I'm going to answer to the best I can.</p> <p>4 Q Sure.</p> <p>5 A So with FTIR I would -- if I did -- maybe I can</p> <p>6 try answering this way.</p> <p>7 If I did FTIR on these scraped fibers, I would</p> <p>8 probably -- I think I would expect to see carboxylate and</p> <p>9 hydroxyl bonds, as we did in the XPS. I would think I would</p> <p>10 see those in the FTIR as well.</p> <p>11 But again, the challenge with the FTIR is that</p> <p>12 there are peaks in the proteins, and there are peaks in the</p> <p>13 oxidized polypropylene that overlap, so it's more difficult</p> <p>14 to say whether it's, you know, specifically from the protein</p> <p>15 or the oxidized polypropylene.</p> <p>16 What the XPS again tells you is the atoms.</p> <p>17 There's so much nitrogen, so much oxygen. That's why we</p> <p>18 chose -- I think FTIR would tell you something, and of</p> <p>19 course we did FTIR in vitro. It's not that we didn't want</p> <p>20 to do it. It's just that we didn't have enough sample.</p> <p>21 Q You relied on your visual observation of the</p> <p>22 scraped AMS explant to satisfy yourself that it had been</p> <p>23 cleaned?</p> <p>24 A I don't think that's -- no, I wouldn't say that.</p> <p>25 I think I answered that earlier. I mean, that's why we</p>

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<p style="text-align: right;">Page 54</p> <p>1 did -- just going back to the paper. That's why we did -- I</p> <p>2 mean, that's why I preferred this more rigorous approach of</p> <p>3 looking at the uncleaned fiber and the scraped in</p> <p>4 considering the differences because -- Dr. Iakovlev cleaned</p> <p>5 it as effectively as he could, but by doing the XPS and</p> <p>6 looking at the atoms and the bonding, you can be much more</p> <p>7 rigorous about it.</p> <p>8 When the nitrogen goes away, I think that's a</p> <p>9 reasonable indication that the protein was removed.</p> <p>10 That's -- so I wouldn't say we relied on visual</p> <p>11 observations. We tested both. That's sort of the basis for</p> <p>12 the conclusions in the paper.</p> <p>13 Q So had you had more sample, would it have been</p> <p>14 your preference to do both FTIR and XPS?</p> <p>15 A We would have liked to have done FTIR. I mean, I</p> <p>16 think in these studies, the more methods you can do, you</p> <p>17 know, reviewers like to see that.</p> <p>18 Like I said, FTIR does give you some information,</p> <p>19 but I think you need other methods in addition to that.</p> <p>20 That's what we attempted to do here.</p> <p>21 Q Okay.</p> <p>22 A To clarify, in-vitro we don't have the</p> <p>23 complication of the protein. FTIR in vitro is a different</p> <p>24 situation. But for explants, as I said in my report, I</p> <p>25 think there are methods that are more specific than FTIR.</p>	<p style="text-align: right;">Page 56</p> <p>1 A Yeah. Those are switched.</p> <p>2 Q Okay. And we decided the XPS and the SEM are</p> <p>3 owned by the University?</p> <p>4 A Yeah. Yeah, those are University resources.</p> <p>5 Q Who owns the FTIR equipment?</p> <p>6 A I'm not sure about that. You'd have to ask Dr.</p> <p>7 Dunn.</p> <p>8 Q Do you know what kind of FTIR equipment he used?</p> <p>9 A I don't know that we go into that in much detail</p> <p>10 in the paper, but...</p> <p>11 Q Did you review any protocols for the FTIR testing</p> <p>12 of the three meshes that are seen in Figure 2 in Exhibit 1?</p> <p>13 A The actual testing the acquisition of the data?</p> <p>14 Q Right.</p> <p>15 A I mean, we talked about it. Dr. Dunn has been</p> <p>16 doing FTIR for a very long time, so he was using methods</p> <p>17 that he's used in the past.</p> <p>18 We didn't necessarily talk about the detailed</p> <p>19 protocol that he used. We talked about the general ideas,</p> <p>20 you know, how he would do the experiment. I mean, I just --</p> <p>21 he has a lot of expertise in that area, so I just relied on</p> <p>22 him to do it. I knew what he was doing, but details of how</p> <p>23 he put the fibers on the instrument, he did all of that.</p> <p>24 Q So these are three different meshes; correct?</p> <p>25 A What are three different meshes?</p>
<p style="text-align: right;">Page 55</p> <p>1 Q Let's go to Exhibit No. 1, please, and go to</p> <p>2 page 7.</p> <p>3 A Okay.</p> <p>4 Q Page 7 in Figure 2 contains FTIR spectroscopy of</p> <p>5 three different meshes over a five-week period; correct?</p> <p>6 A That's right.</p> <p>7 Q And is this testing that people -- Dr. Dunn and</p> <p>8 people under his supervision prepared?</p> <p>9 A Yeah. Dr. Dunn -- to my knowledge, Dr. Dunn ran</p> <p>10 these FTIR spectra.</p> <p>11 Q Okay. And who prepared the text for Figure 2?</p> <p>12 A You mean the caption?</p> <p>13 Q Yeah, bottom of the page on page 7.</p> <p>14 A I would say we wrote that together, probably. I</p> <p>15 mean, it's, you know -- I don't remember who exactly wrote</p> <p>16 it.</p> <p>17 Q Do you see down at the bottom it says, "The</p> <p>18 carbonyl peak is indicated with the black arrow." Do you</p> <p>19 see that?</p> <p>20 A Oh, yeah.</p> <p>21 Q It's a mistake, isn't it?</p> <p>22 A The black arrow, yeah. The carbonyl is the gray</p> <p>23 arrow. It's switched in the caption.</p> <p>24 Q The hydroxyl peak, which is indicated as the gray</p> <p>25 area, is actually the black arrow?</p>	<p style="text-align: right;">Page 57</p> <p>1 Q TVT, ADV and Lynx.</p> <p>2 A Oh, yeah. Yeah, those are the three materials</p> <p>3 that we tested.</p> <p>4 Q And these are three materials that you placed in</p> <p>5 what I'll describe as an oxidated medium?</p> <p>6 A That's right.</p> <p>7 Q And then you took FTIRs before the test began?</p> <p>8 A Yes.</p> <p>9 Q And at week 1, week 3, week 4 and week 5;</p> <p>10 correct?</p> <p>11 A Yeah, that's right.</p> <p>12 Q And do you know how many -- strike that.</p> <p>13 Are you familiar with the term "scaling" as used</p> <p>14 in FTIR?</p> <p>15 A Scaling, that could mean -- what exactly do you</p> <p>16 mean by that?</p> <p>17 Q Do you have any understanding what it might mean</p> <p>18 in the FTIR?</p> <p>19 A It's kind of a broad -- kind of a broad general</p> <p>20 word. I don't -- I'm not sure what exactly you're referring</p> <p>21 to.</p> <p>22 Q That's fine. Do you know who conducted the</p> <p>23 tests, the FTIR tests?</p> <p>24 A Dr. Dunn, I believe.</p> <p>25 Q You mentioned before that it might have been</p>

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<p style="text-align: right;">Page 58</p> <p>1 someone under his direction. Do you know anybody else under</p> <p>2 his direction that might have conducted the test?</p> <p>3 A I don't know. It's been some time. I don't</p> <p>4 know. He would have to answer that. He may have done the</p> <p>5 FTIR spectra himself. He was pretty -- I don't know the</p> <p>6 details of how he actually did it.</p> <p>7 Q Do you know how many scans he ran each week?</p> <p>8 A Other than what's reported in the paper, I don't</p> <p>9 remember those kind of details. Let me see what I wrote.</p> <p>10 We didn't report the number of scans, but again,</p> <p>11 he would have that. I just don't remember how many we did.</p> <p>12 Q Do you know the number of scans that are</p> <p>13 generally regarded as appropriate for reporting FTIR data?</p> <p>14 MR. JACKSON: Objection to form.</p> <p>15 A Not off the top of my head.</p> <p>16 BY MR. THOMAS:</p> <p>17 Q Do you know why you run multiple scans?</p> <p>18 A Well, I mean, I would run multiple scans to --</p> <p>19 you know, that helps you address sort of the error in</p> <p>20 measurement. So I would run multiple scans. I just don't</p> <p>21 know how many he did here. These are details Dr. Dunn would</p> <p>22 have to address.</p> <p>23 Q How many scans would you believe you, Dr.</p> <p>24 Guelcher, believe were appropriate to address the error in</p> <p>25 your measurement?</p>	<p style="text-align: right;">Page 60</p> <p>1 off my memory here -- but it's not related to any of the</p> <p>2 actual bonds that we're looking at in the spectra.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q I understand. Do you have an explanation for</p> <p>5 what happened between week -- from the baseline, week zero,</p> <p>6 and the first week to result in that change in that peak in</p> <p>7 the middle of the week 1 spectra?</p> <p>8 MR. JACKSON: Objection to form.</p> <p>9 A I can't really address that without looking at</p> <p>10 the raw data. Again, this is a published paper. These are</p> <p>11 published data. I said that Dr. Dunn collected all these</p> <p>12 data. I mean, it's kind of hard to go through -- we've seen</p> <p>13 these types of things before.</p> <p>14 BY MR. THOMAS:</p> <p>15 Q Do you know what it is?</p> <p>16 A I think it's carbon dioxide, but I can't remember</p> <p>17 off the top of my head.</p> <p>18 Q Would you defer to Dr. Dunn?</p> <p>19 A Yeah. I know I've seen this before in some of my</p> <p>20 papers where we're looking at isocyanates. Basically,</p> <p>21 sometimes these types of things will happen in the FTIR</p> <p>22 spectra. I can say I don't think this is associated with a</p> <p>23 change in the sample. I think this came up in another</p> <p>24 deposition, to be honest with you. I'm trying to remember</p> <p>25 what I said then, but I don't think it's an actual change in</p>
<p style="text-align: right;">Page 59</p> <p>1 MR. JACKSON: Objection to form.</p> <p>2 A I just don't know off the top of my head. I</p> <p>3 can't remember.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q And what errors can occur in measurement that you</p> <p>6 would need to address with multiple scans?</p> <p>7 MR. JACKSON: Objection to form.</p> <p>8 A I don't know. Just generally speaking, it's just</p> <p>9 good practice just in case there's some artifact in the</p> <p>10 measurement. You run things multiple times. I can't recall</p> <p>11 right now.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q Dr. Guelcher, I want to direct your attention to</p> <p>14 Figure 2, the TVT, which is the top FTIR spectra that's</p> <p>15 listed there.</p> <p>16 A Okay.</p> <p>17 Q Do you see in week 1 that about halfway across</p> <p>18 the scan there's a dip in the spectra? Do you see that?</p> <p>19 A Oh, yeah.</p> <p>20 Q And that is a change from week 1. Do you see</p> <p>21 that?</p> <p>22 MR. JACKSON: Objection, form.</p> <p>23 A Yeah, but I believe you can see peaks like this</p> <p>24 with carbon dioxide. So you basically -- that's not -- we</p> <p>25 can see peaks like that in the spectra -- again, I'm going</p>	<p style="text-align: right;">Page 61</p> <p>1 the material.</p> <p>2 Q Is it a change in the testing environment?</p> <p>3 MR. JACKSON: Objection to form.</p> <p>4 A What do you mean by the environment? Maybe like</p> <p>5 the gas --</p> <p>6 BY MR. THOMAS:</p> <p>7 Q Something about the testing environment that</p> <p>8 altered the FTIR spectra.</p> <p>9 A I just can't remember off the top of my head.</p> <p>10 Q That's fine. Week 3, it looks like that peak</p> <p>11 that we just mentioned in week 1 is gone. Do you see that?</p> <p>12 A Yeah.</p> <p>13 Q And then in week 4 it appears again, but it's</p> <p>14 going a different direction.</p> <p>15 A Yeah, but I don't think this is -- this is -- I</p> <p>16 think you see this in FTIR spectra, and I can't remember the</p> <p>17 details exactly of why it's there, you know. Reviewers</p> <p>18 didn't have a hard time with this. It's not relevant to the</p> <p>19 findings of the carbonyl, and it's in a totally different</p> <p>20 part of the spectra. I mean, it's -- I just don't think</p> <p>21 it's significant. It's not a significant finding. It</p> <p>22 doesn't significantly impact the finding from the FTIR data.</p> <p>23 Q Okay. Doctor, as you look at the TVT mesh, going</p> <p>24 from weeks 1, 2, 3, 4, week 4 in the areas that you're</p> <p>25 looking at, that is, the carbonyl and hydroxyl, week 4 show</p>

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<p style="text-align: right;">Page 62</p> <p>1 no peaks. Do you agree with that?</p> <p>2 A You know, they're not -- if there's a peak there,</p> <p>3 it's not as big as it is in week 5. Week 5 is where we saw</p> <p>4 the peak showing up.</p> <p>5 Q Okay. And you'll agree that the week 4 spectra</p> <p>6 is actually smoother than the spectra from weeks 1 and 3?</p> <p>7 MR. JACKSON: Objection to form.</p> <p>8 A I mean, there's less noise in the --</p> <p>9 BY MR. THOMAS:</p> <p>10 Q Yes.</p> <p>11 A It might appear that way.</p> <p>12 Q Do you have any explanation for that?</p> <p>13 A Again, these are Dr. Dunn's raw data. I can't</p> <p>14 really -- I mean, again, this is peer-reviewed. People</p> <p>15 looked at this and didn't have a problem with it. I mean,</p> <p>16 this is FTIR. You get noisy spectra sometimes.</p> <p>17 Q Is noisy spectra the reason why you do multiple</p> <p>18 scans?</p> <p>19 MR. JACKSON: Objection, form.</p> <p>20 A Could be.</p> <p>21 BY MR. THOMAS:</p> <p>22 Q In any event, you'd defer to Dr. Dunn to answer</p> <p>23 this?</p> <p>24 A I mean, you're going down this line of</p> <p>25 questioning that I'm really -- it's Dr. Dunn's work. It's</p>	<p style="text-align: right;">Page 64</p> <p>1 that you would have showed that this was water confounding</p> <p>2 your FTIR spectra?</p> <p>3 MR. JACKSON: Objection, form.</p> <p>4 A I haven't heard that before. I don't know how</p> <p>5 they could make that opinion without seeing the spectra. I</p> <p>6 haven't seen that.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q You haven't seen that?</p> <p>9 A No.</p> <p>10 Q All right. But any questions in that regard</p> <p>11 would be best directed to Dr. Dunn?</p> <p>12 A You're just going to have to talk to Dr. Dunn</p> <p>13 because that's not -- I didn't do it. I think the question</p> <p>14 that we're going after in the papers was clear, and we</p> <p>15 explained the methods we used, and reviewers accepted it.</p> <p>16 There were no concerns about this. That's why it got</p> <p>17 published.</p> <p>18 And those types of detailed questions about the</p> <p>19 data and how far you ran the spectra, Dr. Dunn would be the</p> <p>20 one that would have to answer that. It's not my data.</p> <p>21 Q If you go to the Lynx mesh in Figure 2, week 4,</p> <p>22 you agree that they show no peaks either at the carbonyl or</p> <p>23 the hydroxyl peak?</p> <p>24 A You know, again, same as before. I don't know</p> <p>25 that I'd say there's no peak, but it's much smaller.</p>
<p style="text-align: right;">Page 63</p> <p>1 kind of hard for me to speculate on these things.</p> <p>2 Q Okay. Now, for all three of these spectra --</p> <p>3 actually, there are 15 spectra, three different devices,</p> <p>4 five spectra for each. The spectra themselves are</p> <p>5 truncated. They're stopped at about the 1,100 level. Do</p> <p>6 you see that?</p> <p>7 A Yeah.</p> <p>8 Q Why is that?</p> <p>9 A Well, again, the peaks that we were interested in</p> <p>10 were the carbonyl and hydroxyl. And just to make it easier</p> <p>11 for the reader to read the paper, in that range of the</p> <p>12 spectrum we're not necessarily expecting changes, so they're</p> <p>13 not shown here.</p> <p>14 Now, whether Dr. Dunn went out to those wave</p> <p>15 numbers, I don't know. But what we tried to show here,</p> <p>16 these are representative spectra to give the reader of the</p> <p>17 paper an idea of the changes that we saw. That's the</p> <p>18 purpose of this figure. So over what range he ran it, I</p> <p>19 don't know. You'd have to talk to him.</p> <p>20 Q Okay. Have you ever seen spectra for the meshes</p> <p>21 that are depicted in Figure 2 that are complete FTIR</p> <p>22 spectra?</p> <p>23 A A can't remember. I don't know.</p> <p>24 Q Do you remember Dr. Thames and Dr. McLean opining</p> <p>25 in their report that had you displayed the additional data</p>	<p style="text-align: right;">Page 65</p> <p>1 Q And then in week 5 there's, at least for the</p> <p>2 Lynx, there's a much larger change than either the ADV or</p> <p>3 the TVT. Do you agree with that?</p> <p>4 A Yeah, that peak is bigger.</p> <p>5 Q Do you have any reason or opinion about why the</p> <p>6 peaks that you found in the Lynx are so much higher and</p> <p>7 bigger than the peaks that you found in either the ADV or</p> <p>8 the TVT?</p> <p>9 A No, that really wasn't the purpose of the paper.</p> <p>10 The purpose of the paper was not to compare meshes. The</p> <p>11 purpose of the paper was to answer the question whether mesh</p> <p>12 stabilized with antioxidants can oxidize. That was the</p> <p>13 question.</p> <p>14 We were not trying to look for differences</p> <p>15 between the meshes. That was -- that's not a question we</p> <p>16 were really addressing.</p> <p>17 Q But does this analysis -- strike that. But the</p> <p>18 three meshes were both subjected to the same conditions?</p> <p>19 A Yeah.</p> <p>20 Q And the same tests?</p> <p>21 A Yeah.</p> <p>22 Q So is it unreasonable to compare the finding in</p> <p>23 week 5 to the TVT to the finding in week 5 to the Lynx?</p> <p>24 A Well, you can make whatever comparison you want,</p> <p>25 but that's not a question we're going after in this study.</p>

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<p>1 That wasn't -- you know, we weren't trying to make 2 comparisons between different types of mesh. 3 We were just -- we know that they're all 4 stabilized with antioxidants, so we were asking the 5 question, can it happen? It happened in all three of them. 6 That's what I can say. 7 Q Okay. Now, based on past litigation, I know that 8 you're aware of the antioxidants that are contained in TVT. 9 A Yes. 10 Q Are you aware of the antioxidants that are 11 contained in Boston Scientific? 12 A I'm aware of them. I don't remember exactly what 13 they were and can't really -- even if I did, I can't really 14 say what they are. I believe that I have seen those 15 formulations. 16 Q Is it different than the TVT? 17 A I can't remember. 18 Q Do the different peaks that you see in weeks 5 19 for the TVT and the Lynx tell you anything about the 20 differences in the mesh? 21 A Again, I think -- I thought I answered that. I'm 22 not willing to -- based on these data, that's not discussed 23 in the paper. That's not a question we were trying to 24 answer. I'm not going to look at these spectra and conclude 25 that there were significant differences because that's not a</p>	<p>1 A It what? 2 Q I haven't talked to you about the Talley paper 3 before. I've never asked you questions about that before. 4 A No, but some other Ethicon attorneys have. 5 Q Not in the context of Talley? 6 A No, but it's the same answer. I've been asked 7 about this medium before. I mean, the medium simulates the 8 microenvironment between the macrophage and the adherent -- 9 well, I didn't answer that very well. It simulates the 10 environment between the macrophage and polypropylene 11 surface. 12 MR. THOMAS: Let me show you Exhibit No. 4. 13 (Exhibit 4 was marked for identification.) 14 BY MR. THOMAS: 15 Q This is the paper that we've talked about before; 16 correct? 17 A Yeah. This isn't a paper. This is a published 18 conference proceedings. 19 Q Just so we're clear, you don't rely upon this 20 test and this data in the opinions that you're giving in 21 this case; correct? 22 MR. JACKSON: Objection to form. 23 A I don't remember if I cited it in the report, but 24 this is a conference proceedings that was published before 25 the paper. So the paper basically, I think, includes all of</p>
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<p>1 question we were testing. That's outside of scope of what 2 we did. 3 Q Okay. 4 A Anybody can look at that and draw any opinion 5 that they want, but that's not my opinion. I don't have an 6 opinion about that. 7 Q That's fine. Now, the analysis that you show in 8 Figure 2, is it fair to describe this as an accelerated 9 oxidation study? 10 MR. JACKSON: Objection, form. 11 A I've answered this before, too, but I don't know 12 that I would use the term "accelerated." 13 I mean, essentially I think the way I've answered 14 this before is that you -- this medium simulates that 15 privileged pocket between the macrophage and the material 16 surface, and so it's essentially like you're exposing the 17 entire material to that privileged environment. 18 So I don't know that I'd call it accelerated. I 19 think what this method does is, it produces hydroxyl 20 radicals, which are reactive oxygen, and so it simulates 21 what can happen in the body. That's what I think has been 22 published about this medium, and I've published other papers 23 on it. We talked about it before. 24 Q That was the prior paper that you presented, 25 different organizations, correct?</p>	<p>1 these data. I haven't looked at it recently, but I believe, 2 just looking at it right now, the paper includes the data in 3 this conference proceedings. 4 So I don't want to say I'm not relying on it, but 5 it's, you know, it's a paper -- most of what's in this 6 abstract is incorporated in the paper. 7 MR. JACKSON: I just want to state for the record 8 this was Exhibit 3 at his last deposition. 9 MR. THOMAS: I understand that. The reason why I 10 asked is because I understood -- 11 THE WITNESS: I'm not sure what you're getting 12 at, I guess. 13 MR. THOMAS: I'm not either. I don't want to 14 plow old ground. 15 THE WITNESS: I understand that. I'm not sure 16 what you're asking. 17 MR. THOMAS: I didn't take the last deposition. 18 I think Mr. Hutchinson did. 19 BY MR. THOMAS: 20 Q Let me back up because I think I may be talking 21 about different things. 22 A Okay. 23 Q There is yet other papers about other work that 24 you did that you presented I think in Europe, and that was 25 the subject of a motion in the Boston Scientific litigation,</p>

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<p style="text-align: right;">Page 70</p> <p>1 and after that time you stopped relying upon that data in 2 your opinions in the case.</p> <p>3 MR. JACKSON: I'm going to object to form of the 4 last question. I think we're getting pretty far afield 5 here. We're talking about a different litigation.</p> <p>6 MR. THOMAS: All I'm trying to do, Tim, is to 7 limit his opinions because -- I don't mean to make it a 8 speech, but I'm trying to shortcut this.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q You did some earlier work that you presented, and 11 we went through the background data. We went through all 12 the stuff.</p> <p>13 A I think I know where you're going.</p> <p>14 Q At some point you stopped relying on that data in 15 your opinions in the case. All I want to do is establish 16 that you haven't changed your mind and are now relying on 17 testing and results that you reported before and presented 18 before that you previously withdrew.</p> <p>19 A I know this is your question on the table. It 20 would really help me out to just deal with this head-on if I 21 could talk with counsel for a few minutes.</p> <p>22 Q Sure.</p> <p>23 MR. JACKSON: Could we take a two-minute break?</p> <p>24 THE WITNESS: I'm not trying to give you a hard 25 time.</p>	<p style="text-align: right;">Page 72</p> <p>1 was in those test data. I don't think we had a lot of the 2 analysis that we presented in this paper.</p> <p>3 Q Exactly right.</p> <p>4 A So the raw data we looked at and did some 5 additional analysis and thinking and submitted paper, a 6 publication which was peer-reviewed and published. So we 7 did not repeat the experiment, but we did more work on the 8 analysis to basically present the paper in a form that could 9 be published.</p> <p>10 Q Right. To be fair, I think the XPS data is new?</p> <p>11 A I believe it is, but I can't remember exactly 12 what was in that report.</p> <p>13 Q And the AMS explant analysis is new?</p> <p>14 A I don't think that was in any test data -- I 15 can't remember. To the best of my knowledge, I believe it's 16 new, but I just can't remember what Dr. Dunn disclosed in 17 his test data.</p> <p>18 Q Okay. Dr. Guelcher, if you look back at Figure 2 19 on page 7, the carbonyl peaks that are there that are 20 mislabeled with the gray arrow, do you know if those 21 carbonyl peaks appear at the same place for each mesh?</p> <p>22 A I'd have to go back and look at the raw data. 23 There are multiple -- there can be multiple carbonyl peaks. 24 I can't remember if they're different for each. 25 Again, that's not what -- we weren't answering</p>
<p style="text-align: right;">Page 71</p> <p>1 MR. THOMAS: I'm not worried about that because I 2 want to make this quick and easy too. Let's go off the 3 record.</p> <p>4 (Recess was taken from 10:22 to 10:32.)</p> <p>5 BY MR. THOMAS:</p> <p>6 Q Doctor, are the FTIR spectra that are on Figure 2 7 of Exhibit No. 1 the result of tests that we've previously 8 discussed in deposition, or have you done a second set of 9 tests?</p> <p>10 A No, we haven't done a second set of tests.</p> <p>11 Q Okay. Just so we're clear -- and I think we 12 talked about this before because I think I asked you 13 questions about it -- some time ago you conducted a 14 five-week oxidation study that you presented at least at one 15 conference and disclosed those opinions in an expert report; 16 correct?</p> <p>17 A That's right.</p> <p>18 Q After the disclosure of those expert opinions, 19 for whatever reason you stopped relying upon the test 20 results in that report for your opinions.</p> <p>21 A Yes. Yeah, I didn't rely on the test data.</p> <p>22 Q Is it fair to understand that now that the data 23 has been published that you are now relying on that data for 24 your opinions in this case?</p> <p>25 A I don't -- well, I don't remember exactly what</p>	<p style="text-align: right;">Page 73</p> <p>1 that question in this paper, so I really don't think we 2 looked at it. We were just looking at that -- well, we 3 explained what we did. 1,500 to 1,750 is where you'll see 4 those carbonyl peaks, and we weren't looking for differences 5 between products or materials.</p> <p>6 Q You agree that an FTIR is designed to generate a 7 fingerprint for a particular substance?</p> <p>8 A I don't know that I'd say it that way. Basically 9 the FTIR gives you information about bonds based on 10 vibration frequencies. But carbonyls -- I mean, I think 11 this has come up in previous depositions -- there can be 12 multiple peaks. This is all even in some of the Ethicon 13 documents that I cite in my report. There can be multiple 14 carbonyl peaks, and we just didn't look for differences 15 between materials.</p> <p>16 Q Would you expect polypropylene in different 17 meshes that are exposed to the exactly the same conditions 18 as you did in your study in Exhibit 1 to display the same 19 carbonyl peak if in fact it was oxidized polypropylene?</p> <p>20 A I'm going to have to go to my report for that 21 one. I know that it's in here.</p> <p>22 I think the best I can answer is like I did. 23 There are multiple species. There are a number of Ethicon 24 documents reporting different carbonyl peaks that could be 25 resulting from different species. I wouldn't necessarily</p>

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<p style="text-align: right;">Page 74</p> <p>1 expect different materials from different manufacturers to</p> <p>2 have different peaks. I can't rule it out. I don't know</p> <p>3 that -- it's just, there's just multiple species, and it can</p> <p>4 be difficult to assign some of them to specific bonds, you</p> <p>5 know, real precisely.</p> <p>6 This goes back to what I was saying about the</p> <p>7 difference between XPS and FTIR. I mean, I can say broadly</p> <p>8 that if the polypropylene is oxidizing based on reaction</p> <p>9 mechanism, I would expect to see carbonyl peaks, and that's</p> <p>10 what we tested in this paper, but we just weren't looking at</p> <p>11 that level of detail for differences between groups.</p> <p>12 Q I want to talk now about the AMS explant that</p> <p>13 Dr. Iakovlev supplied. Do you know how he scraped it?</p> <p>14 A Again, you'd have to talk to him about those</p> <p>15 details. I think you know Dr. Iakovlev's papers, but he</p> <p>16 prefers to work with dry mesh to get around this protein</p> <p>17 cross-linking issue that Dr. Thames referred to.</p> <p>18 So Dr. Iakovlev has been doing it for some time.</p> <p>19 I've seen his microscope. I've seen his lab. Exactly how</p> <p>20 he does that procedure, I don't have the details.</p> <p>21 Q It's fair to understand, from a review of</p> <p>22 Exhibit 1 or Exhibit 2, there's no way for another</p> <p>23 researcher to replicate this cleaning technique. Do you</p> <p>24 agree with that?</p> <p>25 A I don't agree with that. I think he gave enough</p>	<p style="text-align: right;">Page 76</p> <p>1 BY MR. THOMAS:</p> <p>2 Q The first page.</p> <p>3 A Yeah, so we don't describe -- referring back,</p> <p>4 this is just supplemental material. So I think the primary</p> <p>5 description of what he did is in the paper.</p> <p>6 Q Okay. Can you tell how much force he used in</p> <p>7 scraping, from the paper?</p> <p>8 A Well, I mean, I think the point of what he was</p> <p>9 trying to do was to be as gentle as possible without --</p> <p>10 basically the purpose is -- you know, when you say the outer</p> <p>11 layers mechanically removed, that means that when you look</p> <p>12 at these under a microscope, you'll see these layers of</p> <p>13 tissue, and you can gently remove them with a pair of</p> <p>14 tweezers. That's what I understand that he did.</p> <p>15 Q How thick is the layer of protein that's absorbed</p> <p>16 onto the mesh material?</p> <p>17 MR. JACKSON: Objection to form.</p> <p>18 A Absorbed, or do you mean adherent protein? I'm</p> <p>19 not sure what you mean.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q I'll use your term, "adherent protein." How</p> <p>22 thick was that layer?</p> <p>23 A I'm not sure.</p> <p>24 Q On the order of a few microns?</p> <p>25 A I don't know.</p>
<p style="text-align: right;">Page 75</p> <p>1 detail in the paper that obviously satisfied the reviewers</p> <p>2 as to how those materials can be cleaned. He manually</p> <p>3 dissected it under a microscope with tweezers and a scalpel</p> <p>4 blade. I think that can be replicated. I don't see a</p> <p>5 problem with that.</p> <p>6 Q With all due respect, the only place I saw for a</p> <p>7 description of his methodology is on page 1 of Exhibit 2.</p> <p>8 A I was looking at page 5 in the paper where he</p> <p>9 says -- the X-ray photoelectron spectroscopy paragraph, he</p> <p>10 says, "Scraped fibers in which the outer layer was</p> <p>11 mechanically removed using tweezers and a scalpel blade</p> <p>12 under dissection microscope."</p> <p>13 Q Is that the extent of methodology that you're</p> <p>14 aware of?</p> <p>15 MR. JACKSON: Objection to form.</p> <p>16 A Yeah. I mean, I think it sounds pretty</p> <p>17 straightforward. He's been doing it for some time. The</p> <p>18 reviewers were fine with it. I mean, it's a mechanical</p> <p>19 dissection of tissue. People do that.</p> <p>20 Again, if you wanted all the details, if he has a</p> <p>21 protocol and all that, he would have to address that. I</p> <p>22 mean, I think for a paper, this is a reasonable description</p> <p>23 of the methodology. I'm looking on Exhibit 2 to see what's</p> <p>24 written there.</p> <p>25</p>	<p style="text-align: right;">Page 77</p> <p>1 Q Do you know how thick the blade is on a scalpel</p> <p>2 that he used, how it compares to the thickness of the</p> <p>3 proteins on the mesh?</p> <p>4 A I don't. Again, these types of detailed</p> <p>5 questions -- I don't know those types of details. Dr.</p> <p>6 Iakovlev did this, and I can't speculate on those types of</p> <p>7 things.</p> <p>8 Q Was there any consideration to testing the</p> <p>9 scraped mesh explant for other oxygen-containing molecules</p> <p>10 such as esters or cholesterol?</p> <p>11 A Well, I mean, again, we have to rely on what the</p> <p>12 XPS can tell us, and the XPS can tell us information about</p> <p>13 atoms that are there and the bonding. So esters are going</p> <p>14 to have carbonyl groups in them. It tells us about what</p> <p>15 molecules are there and the way that they're bound to each</p> <p>16 other.</p> <p>17 Q So you're looking at the data on the table that's</p> <p>18 on page 4, Exhibit No. 2?</p> <p>19 A I was referring back.</p> <p>20 Q Is there anything about the data on page 4 of</p> <p>21 Exhibit No. 2 that tells you that the oxygen that was found</p> <p>22 on the mesh explant was not an ester or a cholesterol?</p> <p>23 A I mean, it is an ester. I mean, I'm not sure</p> <p>24 what you mean by ester. I mean, it's an ester bond. I</p> <p>25 mean, it's -- well, it's not ester bond. It's a COO.</p>

20 (Pages 74 to 77)

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<p style="text-align: right;">Page 78</p> <p>1 That carbonyl is present in an ester. If you 2 look at the degradation products -- I have to go back to 3 this. So I see what you're saying. I mean, an ester bond 4 would also have that carbonyl. It could also be, I think, 5 carboxylate. So it's not -- the XPS is just telling you 6 about those specific types of bonds. So, like in protein, 7 you could have esters, right. So it's -- I'm not being very 8 clear.</p> <p>9 The XPS tells you again about the type of bond. 10 You could have a carbonyl and an ester bond. It's also 11 present in the degradation of product from the 12 polypropylene.</p> <p>13 Q Right. And cholesterol may also appear in the 14 carbonyl group?</p> <p>15 A Maybe. I'd have to look at the structure.</p> <p>16 Q Why didn't you do a controlled experiment on a 17 pristine AMS mesh?</p> <p>18 A What do you mean by "controlled experiment"?</p> <p>19 Q Do the same testing XPS on a pristine AMS mesh.</p> <p>20 A I don't remember.</p> <p>21 Q Did you have that discussion?</p> <p>22 A I don't remember.</p> <p>23 Q Did you have pristine AMS mesh available to you?</p> <p>24 A I don't remember that either. Dr. Dunn had all 25 those materials. So I can't remember that one either.</p>	<p style="text-align: right;">Page 80</p> <p>1 BY MR. THOMAS:</p> <p>2 Q Doctor, would you turn to page 6 of Exhibit 1. 3 Page 6 of Exhibit 1 includes a paragraph called "Surface 4 degradation caused by SEM."</p> <p>5 A Yes.</p> <p>6 Q And who conducted this work?</p> <p>7 A Dr. Dunn.</p> <p>8 Q Do you know what kind of scanning electron 9 microscope was used?</p> <p>10 A That's hard to answer. We've replaced that 11 instrument at Vanderbilt. I can't remember where we were on 12 that when this work was done. Maybe -- well, let me see. 13 It might say in the -- we have several different SEMs. It's 14 Hitachi. We have a newer one now, I think.</p> <p>15 Q What is it about the Hitachi SEM that allows 16 measurement of peak depth?</p> <p>17 A Peak depth?</p> <p>18 MR. JACKSON: Objection to form.</p> <p>19 A Well, we used --</p> <p>20 BY MR. THOMAS:</p> <p>21 Q You have a number of measurements in this 22 paragraph going from 1 micron to 10 microns. How are you 23 able to measure that?</p> <p>24 A Well, I mean, as you can see, these are -- we're 25 saying greater than -- you know, these are not -- we didn't</p>
<p style="text-align: right;">Page 79</p> <p>1 Q What did you do to rule out contamination of the 2 explant?</p> <p>3 MR. JACKSON: Object to form.</p> <p>4 A Contamination?</p> <p>5 BY MR. THOMAS:</p> <p>6 Q Yes. Something from the environment that didn't 7 come from the mesh when it was implanted in the patient.</p> <p>8 A I mean, we use standard methodology for XPS 9 analysis, according to Dr. Rogers' papers. We removed the 10 protein mechanically the best we could. We tested, compared 11 the untreated to the treated -- and I'm sorry -- untreated 12 to the scraped. That's what we can do. I mean, we have no 13 evidence to believe there was significant contamination that 14 would alter the results.</p> <p>15 Q But you didn't take any steps to confirm that the 16 AMS explant had not been contaminated?</p> <p>17 MR. JACKSON: Objection to form.</p> <p>18 A I'm not really sure. Again, Dr. Rogers did that 19 work. It's difficult for me to -- I mean, we used existing 20 methods that we've used before to clean the mesh and to 21 analyze it. Dr. Rogers has published on XPS. I've 22 published with her on XPS. We use standard methods and 23 protocols for doing that work. There's no evidence to 24 suggest there was contamination. So that's kind of the way 25 the science is done.</p>	<p style="text-align: right;">Page 81</p> <p>1 do statistical analysis on these measurements.</p> <p>2 So the flaking, we have a scale bar on the SEM, 3 and you can see that those flakes and peeling features are 4 greater than 10 microns based on that scale bar. The depth 5 of the pits is a little bit more difficult. You could 6 estimate that to be in the range of a micron. We were just 7 trying to give some idea of the length scale of the 8 features.</p> <p>9 Q Is it fair to say the numbers there are 10 estimates?</p> <p>11 A I would say they're semiquantitative numbers 12 based on the images that are shown in the paper.</p> <p>13 Q If you go to page 9, there are scanning electron 14 microscopy images. Are there more images than what are 15 contained in the report?</p> <p>16 A So, I mean, it's the same for Figure 2. These 17 are representative images to give the reader some 18 perspective on what we saw. We -- I think we list them in 19 the report. I'm sorry. I keep saying -- this is a paper.</p> <p>20 Q I understand.</p> <p>21 A A published paper. I'm getting confused. So in 22 this paper we are -- so I basically -- we used low, medium, 23 high-magnification images. I think in the methods we 24 discussed how many images we took of each one, 5 to 15 25 images of each specimen. It just depended, it seems, on the</p>

21 (Pages 78 to 81)

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<p style="text-align: right;">Page 82</p> <p>1 specimen. So we have multiple images. These are</p> <p>2 representative ones to give some perspective on what we saw.</p> <p>3 Q And you would expect Dr. Dunn to have those</p> <p>4 images?</p> <p>5 A Yeah.</p> <p>6 Q Was he the one that provided the measurements and</p> <p>7 data that went into the paragraph I've just described on</p> <p>8 page 6?</p> <p>9 A That was probably me. I can't remember exactly.</p> <p>10 I probably did that.</p> <p>11 Q How did you do that? By looking at the scale</p> <p>12 bars?</p> <p>13 A Yeah. So you can look at the scale bar, and you</p> <p>14 can kind of draw a line on the feature. You can see that</p> <p>15 it's -- the purpose of like the greater than is to show that</p> <p>16 it is semiquantitative. We're giving some idea of a length</p> <p>17 scale. We didn't do specific measurements on those</p> <p>18 features. We just were trying to provide some perspective</p> <p>19 on the length scale.</p> <p>20 Q So other than the scale within the SEM itself,</p> <p>21 there was no effort to have a more precise measurement?</p> <p>22 MR. JACKSON: Objection to form.</p> <p>23 A You know, it's just difficult to measure that.</p> <p>24 The depth of a pit, you know, you could do profilometry, but</p> <p>25 it's not a flat surface. It's difficult to measure that</p>	<p style="text-align: right;">Page 84</p> <p>1 contractile forces from cells that infiltrate the mesh. So</p> <p>2 it's a combination of those forces and the chemical</p> <p>3 environment, chemical degradation that causes those cracks,</p> <p>4 and we believe that's why we didn't see it. That's what</p> <p>5 this discussion is saying.</p> <p>6 Q Was there anything about this experiment that</p> <p>7 prevented you from including some application mechanical</p> <p>8 force to try to replicate the transverse cracks?</p> <p>9 A Well, it can be done. It's just this was a first</p> <p>10 step. I mean, the first question we wanted to answer really</p> <p>11 is, can something oxidize? That was a question in this</p> <p>12 paper.</p> <p>13 I mean, to answer the cracking question, you</p> <p>14 would have to include some kind of stretching protocol, and</p> <p>15 that takes considerably more resources, time, effort and</p> <p>16 work. And we thought it made sense to start with the</p> <p>17 oxidation question since, you know, the degradation is a</p> <p>18 consequence of the oxidation. So that's why we started with</p> <p>19 that question, and that's why we didn't do mechanical forces</p> <p>20 in this study.</p> <p>21 Q Do you have plans to do any further study which</p> <p>22 would include the application of forces to try to replicate</p> <p>23 the transverse cracking?</p> <p>24 A I mean, these are research studies that are</p> <p>25 funded by external sponsors, so I can't really talk about</p>
<p style="text-align: right;">Page 83</p> <p>1 depth precisely. So we were doing the best we could from</p> <p>2 these images.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q And using the scale that's in there?</p> <p>5 A Yeah.</p> <p>6 Q Do you recognize in the paper that the flaking</p> <p>7 and pitting that you observed and report on page 9 in the</p> <p>8 SEMs is different from the transverse tracking that's been</p> <p>9 reported in other papers; correct?</p> <p>10 MR. JACKSON: Counsel, when you say "report,"</p> <p>11 we're talking about the published paper, right?</p> <p>12 BY MR. THOMAS:</p> <p>13 Q Dr. Guelcher, it's fair to understand that you</p> <p>14 reference in your paper the fact that the flaking and the</p> <p>15 pitting that you report and show in Figure 3 on page 9 of</p> <p>16 this paper is different from the transverse cracking that</p> <p>17 has been reported by others?</p> <p>18 A I think we addressed that in the discussion. So</p> <p>19 there's some -- yeah, so the last paragraph of discussion,</p> <p>20 you know, the point that we're making there is, this</p> <p>21 corrosion and stress cracking can happen when you have a</p> <p>22 combination of mechanical forces and chemical degradation,</p> <p>23 and in this experiment we only had chemical degradation.</p> <p>24 So we would not expect to see necessarily those</p> <p>25 transit cracks. It's the combination of forces, say</p>	<p style="text-align: right;">Page 85</p> <p>1 what we're doing.</p> <p>2 Q You can't answer the question?</p> <p>3 A No, I can't. It's research. I mean, I can't</p> <p>4 really talk about any research that we're doing. For this</p> <p>5 Wave 5 report on the line and these documents we've been</p> <p>6 talking about -- I just can't really talk about what we're</p> <p>7 doing right now. We're not relying on it.</p> <p>8 Q Do you have ongoing studies into the oxidation of</p> <p>9 polypropylene?</p> <p>10 A I just can't talk about it.</p> <p>11 Q Can you answer yes or no?</p> <p>12 A No, I can't answer yes or no. I can't really</p> <p>13 talk about what we're doing. It's an externally funded</p> <p>14 research project. It's confidential.</p> <p>15 Q Can you tell me who's funding the research</p> <p>16 project?</p> <p>17 A I mean, I never said there was a research</p> <p>18 project. I'm saying that, you know, our plans and ideas,</p> <p>19 these are all -- it's research. It's confidential.</p> <p>20 Q Okay. We may have to come back to that. How do</p> <p>21 you measure embrittlement?</p> <p>22 MR. JACKSON: Objection, form.</p> <p>23 A I think it's in my report, but I'll --</p> <p>24 embrittlement you could -- you could measure by mechanical</p> <p>25 testing, dynamic mechanical testing. It's a mechanical-type</p>

22 (Pages 82 to 85)

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<p>1 test.</p> <p>2 BY MR. THOMAS:</p> <p>3 Q Have you done any embrittlement testing of any of</p> <p>4 the meshes that you've tested in Exhibit No. 1?</p> <p>5 A We have not. Again, it's a very technically</p> <p>6 challenging test to do, so we decided to start with things</p> <p>7 we could do using known and established methods.</p> <p>8 Embrittlement requires a certain kind of -- it</p> <p>9 would be more difficult to do, and we have to -- we haven't</p> <p>10 done it.</p> <p>11 MR. THOMAS: Let me take a break. Give me a few</p> <p>12 minutes. I may be close to wrapping up.</p> <p>13 MR. JACKSON: All right.</p> <p>14 (Recess was taken from 11:00 to 11:05.)</p> <p>15 (Exhibit 5 was marked for identification.)</p> <p>16 BY MR. THOMAS:</p> <p>17 Q I'm going to hand you now what's been marked as</p> <p>18 Deposition Exhibit Number 5, the Second Amended Notice of</p> <p>19 Deposition. This requested that you bring with you to the</p> <p>20 deposition a number of things. I've received the filing by</p> <p>21 your counsel about objections. I've also received some</p> <p>22 billing information, a copy of the 2017 published article,</p> <p>23 which is Exhibit 1, supplemental data which is Exhibit</p> <p>24 Number 2.</p> <p>25 There is a deposition request that you also</p>	<p>1 A Maybe a year ago. No, six months. Within a</p> <p>2 year.</p> <p>3 Q What does she do for FDA?</p> <p>4 A She is a reviewer of medical device applications.</p> <p>5 Q Where does she work in Maryland?</p> <p>6 A She works at FDA.</p> <p>7 Q I understand that, but Maryland is a big state.</p> <p>8 I don't mean to be flip, but I'm just trying to find out</p> <p>9 which city.</p> <p>10 A I don't know. I don't know where exactly she</p> <p>11 lives.</p> <p>12 Q Is it closer to Washington D.C. or closer to</p> <p>13 Baltimore? Do you have any idea?</p> <p>14 A Probably D.C.</p> <p>15 Q And Dr. Rogers still work at Vanderbilt?</p> <p>16 A Yes.</p> <p>17 Q Dr. Dunn still at Vanderbilt?</p> <p>18 A Yes.</p> <p>19 Q Were you the person who was responsible for</p> <p>20 organizing the study?</p> <p>21 MR. JACKSON: Objection, form.</p> <p>22 A I would say that Dr. Dunn and I did that</p> <p>23 together. We thought about what question we want to ask,</p> <p>24 how we could design the study, then we maybe talked to Dr.</p> <p>25 Iakovlev about explants.</p>
Page 87	Page 89
<p>1 produce all of the underlying data for the Exhibit Number 1</p> <p>2 and Exhibit No. 2, and I believe we've covered that today in</p> <p>3 your deposition, that is, to the extent that that data is</p> <p>4 available, it's in the custody or control of the people who</p> <p>5 conducted the work and not in your current possession. Is</p> <p>6 that fair?</p> <p>7 A That's right.</p> <p>8 Q And you did not ask them to give that information</p> <p>9 to you for purposes of this deposition; correct?</p> <p>10 A I did not because that's just not how things are</p> <p>11 done. I think if you want somebody's data, you have to ask</p> <p>12 them directly.</p> <p>13 Q Have you had any -- as corresponding author, have</p> <p>14 you had any inquiries about the work that went into the</p> <p>15 Talley study?</p> <p>16 A I've had requests for the paper, and I've sent</p> <p>17 that to people, but I haven't had any detailed questions</p> <p>18 about it.</p> <p>19 Q Other than producing the paper, have you</p> <p>20 discussed with anybody else your methodology or the results</p> <p>21 that you've reached?</p> <p>22 A Not that I can remember.</p> <p>23 Q Where does Ms. Talley live now, Dr. Talley?</p> <p>24 A She lives in Maryland. She works for FDA.</p> <p>25 Q When did she take her job with FDA?</p>	<p>1 So probably mostly it was probably Dr. Dunn and</p> <p>2 me planning the study.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q On page 13 of Exhibit No. 1 under the disclosure</p> <p>5 statement and funding it says, "Russell F. Dunn is the owner</p> <p>6 of Polymer Chemical Technologies, which sponsored the work."</p> <p>7 A Yes.</p> <p>8 Q Are there other employees of Polymer Chemical</p> <p>9 Technologies, to your knowledge?</p> <p>10 A I don't know at the moment. You would have to</p> <p>11 ask Dr. Dunn about that. I don't know if he has any</p> <p>12 employees right now.</p> <p>13 Q There's been a time when that was just him?</p> <p>14 A I mean, his business has changed over the years.</p> <p>15 Sometimes he's had employees, sometimes not. So I don't</p> <p>16 know right now. When this work was done, I don't know.</p> <p>17 Q The work was supported by Polymer and Chemical</p> <p>18 Technologies, LLC, Grant Number VU1349. Did you prepare a</p> <p>19 grant request to Polymer and Chemical Technologies for this</p> <p>20 work?</p> <p>21 A No.</p> <p>22 Q What is -- is VU Vanderbilt University?</p> <p>23 A Yes.</p> <p>24 Q So how does Vanderbilt University 1349 obtain a</p> <p>25 grant from Polymer and Chemical Technologies?</p>

23 (Pages 86 to 89)

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<p>1 A I mean, any company can enter into an agreement</p> <p>2 called a sponsored research agreement. I've done this</p> <p>3 before with other companies. Any company can enter into an</p> <p>4 agreement with the University to sponsor research. It's a</p> <p>5 standard thing.</p> <p>6 Q Is it your suggestion that Vanderbilt is a</p> <p>7 sponsor of this research?</p> <p>8 A No.</p> <p>9 Q Okay.</p> <p>10 A It's a sponsored research agreement so an</p> <p>11 external sponsor -- could be a foundation, could be federal</p> <p>12 government, could be a company -- enters into a contractual</p> <p>13 relationship with Vanderbilt University where they agree to</p> <p>14 sponsor research at Vanderbilt. So they pay for the</p> <p>15 research, but the research is done at Vanderbilt. So</p> <p>16 there's a contract that regulates that.</p> <p>17 Q So there's a contract for this study between</p> <p>18 Polymer Chemical Technologies and Vanderbilt University?</p> <p>19 A I don't know if it's for the study. Again, you'd</p> <p>20 have to ask Russell about the details of how his company --</p> <p>21 his relationship between his company and Vanderbilt is</p> <p>22 something I can't really address.</p> <p>23 What I can tell you is that when this says Grant</p> <p>24 Number VU1349, that means that there's some sponsored</p> <p>25 research agreement between Polymer Chemical Technologies and</p>	<p>1 He's the owner, as it says here. I don't -- I don't know --</p> <p>2 I mean, I can't answer these questions. You're asking</p> <p>3 questions about how Polymer Chemical Technologies, who I</p> <p>4 have no relationship with, is doing business. I can't</p> <p>5 answer that.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q I asked you whether you've been party to any</p> <p>8 conversations where it was determined that lawyers in this</p> <p>9 litigation would fund Polymer Chemical Technologies, LLC to</p> <p>10 supply the grant for the work that's done in Exhibits 1 and</p> <p>11 2.</p> <p>12 MR. JACKSON: I think to the extent you're asking</p> <p>13 about conversations between attorneys and the witness,</p> <p>14 that's privileged information.</p> <p>15 MR. THOMAS: Are you directing him not to answer?</p> <p>16 MR. JACKSON: I think he's already answered the</p> <p>17 question.</p> <p>18 MR. THOMAS: Are you directing him not to answer?</p> <p>19 MR. JACKSON: No, I'm not, because I think he's</p> <p>20 already answered the question.</p> <p>21 BY MR. THOMAS:</p> <p>22 Q The question is, have you been party to any</p> <p>23 conversations with lawyers where it's been discussed lawyers</p> <p>24 funding Polymer Chemical Technologies, LLC grant for the</p> <p>25 work that's done in Exhibits Number 1 and 2?</p>
Page 91	Page 93
<p>1 Vanderbilt. The scope of that agreement, I don't know the</p> <p>2 details. That's all I can say from that sentence.</p> <p>3 Q How much was the grant?</p> <p>4 A I don't know.</p> <p>5 Q Was there any other financial support to the work</p> <p>6 in Exhibits Number 1 and 2 beyond what was supplied by</p> <p>7 Polymer and Chemical Technologies, LLC?</p> <p>8 A No.</p> <p>9 Q Do you know whether Polymer and Chemical</p> <p>10 Technologies, LLC obtained money from any other source to</p> <p>11 fund this research?</p> <p>12 A I don't -- again, I don't know the details of how</p> <p>13 the company contracted with Vanderbilt. I don't know those</p> <p>14 details. I can just -- from the way that's written, I can</p> <p>15 infer that there's a contract.</p> <p>16 Q If you had any conversations with any lawyers</p> <p>17 about obtaining money to be supplied to Polymer and Chemical</p> <p>18 Technologies, LLC that would be used as a grant to fund the</p> <p>19 work in Exhibits Number 1 and 2?</p> <p>20 MR. JACKSON: This is clearly privileged</p> <p>21 information you're asking him about.</p> <p>22 MR. THOMAS: Oh, I don't think so.</p> <p>23 MR. JACKSON: No?</p> <p>24 A Again, I have no relationship with Polymer</p> <p>25 Chemical Technologies. This is Russell Dunn's company.</p>	<p>1 A I mean, I can't really discuss all the</p> <p>2 conversations we have with counsel. I mean, I --</p> <p>3 Q He hasn't instructed you not to answer. He's</p> <p>4 permitted you to answer the question.</p> <p>5 MR. JACKSON: I'm instructing him not to answer</p> <p>6 to the extent it calls for any communications between</p> <p>7 himself and attorneys.</p> <p>8 MR. THOMAS: That's fine. We'll fight that one.</p> <p>9 A Let me think about this for a second, all right.</p> <p>10 I'm trying not to --</p> <p>11 MR. JACKSON: I think he's already given you an</p> <p>12 answer to the question.</p> <p>13 MR. THOMAS: I'm not going to argue with you.</p> <p>14 A Let's just -- can we just go with what's written</p> <p>15 here? Can we do that?</p> <p>16 BY MR. THOMAS:</p> <p>17 Q I can read it as well as you can. I'm just</p> <p>18 trying to figure out what else is involved that's not here.</p> <p>19 A Well, what did we disclose? Russell and I --</p> <p>20 Dr. Dunn and I have disclosed these matters to the</p> <p>21 University, and we have -- we have an annual disclosure, and</p> <p>22 all of this has been disclosed.</p> <p>23 In the paper we disclose several things. We say</p> <p>24 that Russell Dunn is the owner of Polymer Chemical</p> <p>25 Technologies. Polymer Chemical Technologies sponsored the</p>

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1 work.	1 ACKNOWLEDGMENT OF DEPONENT
2 I mean, that means that that company, through	2
3 this grant, VU1349, gave money to Vanderbilt, and this work	3 I, SCOTT GUELCHER, Ph.D., do hereby certify that
4 was done within that context.	4 I have read the foregoing pages and that the same is a
5 I don't know the details of that contract. I	5 correct transcription of the answers given by me to the
6 don't know if it funded other work. All I know is, there's	6 questions therein propounded, except for the corrections or
7 a contract between PCT and the University, and this work was	7 changes in form or substance, if any, noted in the attached
8 done within the context of that contract. Dr. Iakovlev and	8 Errata Sheet.
9 I disclosed the fact that we provided opinions in these	9
10 cases. So this is what we disclosed.	10
11 To go into like conversations with attorneys	11
12 about paying for experiments, I can't talk about that.	12
13 That's -- this is, you know, privileged information with	13 SCOTT GUELCHER, Ph.D. Date
14 attorneys.	14
15 Q Okay.	15 Subscribed and sworn to before me this
16 A We did not say that they funded the study. This	16 ___ day of ___, 20__.
17 study was funded by the company. But I can't go any further	17 My commission expires: _____
18 than that. I can't --	18
19 MR. THOMAS: I keep forgetting I've got more time	19
20 than I thought I did. I'm on eastern time. Doctor,	20 Notary Public
21 I'm going to quit. Thank you very much for your time.	21
22 THE WITNESS: Thank you.	22
23 MR. THOMAS: Have a safe trip to Australia.	23
24 MR. JACKSON: I have no questions.	24
25 (Deposition concluded at 11:17.)	25

Page 95	Page 97
1 CERTIFICATE	1
2 I, Gina Hawkins, Licensed Court Reporter for the	2 ERRATA
3 State of Tennessee, do certify that the above deposition was	3
4 reported by me and that the foregoing transcript is a true	4 PAGE LINE CHANGE/REASON
5 and accurate record to the best of my knowledge, skills, and	5
6 ability.	6
7 I further certify that I am not an employee of	7
8 counsel or any of the parties, nor a relative or employee of	8
9 any attorney or counsel connected with the action, nor	9
10 financially interested in the action.	10
11 I further certify that I am duly licensed by the	11
12 Tennessee Board of Court Reporting as a Licensed Court	12
13 Reporter as evidenced by the LCR number following my name	13
14 below.	14
15 Subscribed and sworn to before me when taken this	15
16 17th day of August, 2017.	16
17	17
18	18
19 GINA HAWKINS, LCR #780	19
20 Expiration Date: 6/30/2019	20
21	21
22	22
23	23
24	24
25	25

25 (Pages 94 to 97)

EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

JO HUSKEY AND ALLEN HUSKEY,	:	
Plaintiffs,	:	CASE NUMBER
v.	:	2:12-cv-05201
ETHICON, INC., ET AL.,	:	
Defendants.	:	

TRANSCRIPT OF TRIAL - DAY TWO

AUGUST 25, 2014

BEFORE THE HONORABLE JOSEPH R. GOODWIN,
UNITED STATES DISTRICT JUDGE

Court Reporter:	Carol Farrell, CRR, RMR, CCP, RPR (304)347-3188 carol_farrell@wvsd.uscourts.gov
	Anthony Rolland, CRR, RMR, RPR (407)760-6023 rolland.crr@gmail.com

Proceedings recorded by machine stenography; transcript
produced by computer.

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1 here. This would be considered a large bore mesh, this is a
 2 larger bore mesh. This is the pore size of the TVT-O.
 3 Now, the only reason that I raise that with you is
 4 that in some of the documents that you will see, and maybe
 5 even some of the testimony that you will hear, there's going
 6 to be reference to -- in fact, on the plaintiff's slide they
 7 suggested that there's old construction hernia mesh. There's
 8 a suggestion that the old construction hernia mesh and the
 9 mesh that was used in the TVT-O is somehow a small bore mesh
 10 that has problems with it. And I have to tell you, frankly,
 11 ladies and gentlemen, that there's some sloppy language in the
 12 documents where they refer to it as small bore mesh, probably
 13 because subsequently a larger bore mesh used in other
 14 applications for pelvic or repair surgery and hernia surgery
 15 was developed. The right way to do it would have been to call
 16 it large bore and extra large, or large and larger. But as
 17 you can see how it happens, somebody referred to it as small.
 18 It may be confusing to you when you look at some of the
 19 documents. I'm going to ask you when we talk and look through
 20 the documents and you hear the testimony of some of the
 21 witnesses, it will be important to discern or listen to which
 22 mesh they're actually talking about.
 23 What is important is that it is a large bore mesh.
 24 It was a large bore mesh when initially tested by Dr. Ulmsten
 25 in the mid 1990s, it's still a large bore mesh, and study

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1 after study after study has shown it to be safe and effective.
 2 Now, it's time for me to slow down. This will be the
 3 last time I have an opportunity to address you until at the
 4 end of the case. As Judge Goodwin has told you, the plaintiff
 5 gets to present her evidence first, and I do ask you, as Judge
 6 Goodwin cautioned you, to keep an open mind until you hear
 7 from our witnesses, which will probably be several days from
 8 now.
 9 At the end of this case I think what you will find,
 10 based upon all of the evidence, is that, in fact, the TVT-O
 11 was an appropriate device to treat Ms. Huskey's stress urinary
 12 incontinence, that Ethicon warned of all of the conditions
 13 that Ms. Huskey claims to have experienced, and these were all
 14 done by Dr. Byrkit, and that the product was not defective.
 15 Stress urinary incontinence, ladies and gentlemen, is
 16 a condition for which women need treatment and have been
 17 seeking treatment for decades and decades. The proof will
 18 show that the TVT and the TVT-O were remarkable devices needed
 19 by women and doctors, and that they're safe and effective.
 20 And so at the end of the case, I'll come back to you
 21 and I'll ask you to return a verdict in favor of Johnson &
 22 Johnson and Ethicon.
 23 Thank you.
 24 Thank you, Your Honor.
 25 THE COURT: Ladies and gentlemen of the jury, I

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1 rarely vary from the schedule, but we would barely get the
 2 witness sworn and it would be noon, so we'll be back at five
 3 minutes till one. We'll take a break for lunch.
 4 During the lunch hour do not discuss the case among
 5 yourselves, permit anyone to discuss it with you, or in your
 6 presence. Don't read anything about it, watch anything about
 7 it, listen to anything about it, use any social device, social
 8 media, computer. I think you'll get the drift after I say
 9 this about 50 times. Actually I know you got it the first
 10 time, but I've got to be sure somebody doesn't think I got it
 11 wrong.
 12 Have a good lunch. We'll see you back.
 13 (The Jury left the courtroom at 11:55 a.m.)
 14 THE COURT: Court's in recess.
 15 (A recess was taken at 11:56 a.m.)
 16 (The jury entered the courtroom at 12:55 p.m.)
 17 COURT SERVICES OFFICER: All rise.
 18 THE COURT: Good afternoon. I trust you had a
 19 pleasant lunch. We're ready to begin the presentation of the
 20 evidence.
 21 The plaintiff, if you will call your first witness.
 22 Mr. Wallace?
 23 MR. WALLACE: Yes, Your Honor. Dr. -- the plaintiffs
 24 would call Dr. Scott Guelcher to the stand, please.
 25 THE DEPUTY CLERK: Sir, if you'll please raise your

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1 right hand.
 2 (SCOTT GUELCHER, Ph.D., HAVING BEEN DULY SWORN, TESTIFIED AS
 3 FOLLOWS:)
 4 THE WITNESS: I do.
 5 THE DEPUTY CLERK: Thank you. Please take the
 6 witness stand.
 7 THE COURT: You may proceed.
 8 MR. WALLACE: Thank you, Your Honor.
 9 (DIRECT EXAMINATION OF SCOTT GUELCHER, PH.D., BY MR. WALLACE:)
 10 Q. Could you please introduce yourself to the jury.
 11 A. My name is Scott Guelcher. I'm currently an associate
 12 professor of chemical engineering at Vanderbilt University in
 13 Nashville.
 14 Q. How many years of experience have you had in chemical
 15 engineering?
 16 A. Over 20 years. Yeah.
 17 Q. And have you ever worked with medical device companies
 18 before?
 19 A. Yes, sir. My current research, I'm a professor of
 20 chemical engineering, but my research is in the area of
 21 biomedical materials and a number of these materials, we're
 22 working with companies to determine the products for human
 23 health such as bone void fillers, other types of bone grafts
 24 and products for healing foot ulcers and these types of
 25 products.

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1 Q. Dr. Guelcher, rather than marching through your C.V.,
 2 what I'd like to do is I have prepared a PowerPoint that
 3 outlines some of your qualifications and some of the topics
 4 you'll talk about today. If we could show that on the screen,
 5 please. Counsel?
 6 MR. THOMAS: Do you mind if have a copy?
 7 MR. WALLACE: We are getting a printer.
 8 THE COURT: Do you have -- do you have any problem
 9 with just going ahead?
 10 MR. THOMAS: No, Your Honor.
 11 THE COURT: I figured you looked at it before.
 12 MR. THOMAS: I haven't seen the PowerPoints, but
 13 that's fine. We'll go ahead.
 14 THE COURT: All right. Go ahead.
 15 MR. WALLACE: Thank you, Your Honor.
 16 BY MR. WALLACE:
 17 Q. You've already talked about working at Vanderbilt
 18 University. Can you tell me about the textbook on
 19 biomaterials that's listed there on that slide?
 20 A. So, a number of years ago, I co-edited a textbook on
 21 biomaterials, and this covered a number of different types of
 22 biomaterials that are used for implants and we talked about
 23 properties of the materials that are used in the clinic, and
 24 this was intended primarily as a teaching textbook for
 25 undergraduate and graduate students.

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1 Q. Okay. When you talk about biomaterials, what are you
 2 referring to?
 3 A. So, these are materials that their purpose is to be
 4 implanted in the human body and to serve some goal, either
 5 healing bones, say, or hernia mesh or these different types of
 6 materials that have been designed to achieve a medical goal.
 7 Q. It says that you've given over 200 scientific
 8 presentations. We obviously don't want to hear about all of
 9 them. But can you tell us what you mean when you refer to
 10 scientific presentations?
 11 A. So, these are presentations given in meetings or
 12 scientists working in a certain area. For example, there is a
 13 Society for Biomaterials, and we all meet once a year and
 14 present our latest research, my students and I present at
 15 these meetings, and there is a number of them that are listed
 16 there that I attend regularly.
 17 MR. WALLACE: Can we go to the next slide, please.
 18 THE COURT: Do we have copies for defendants now?
 19 MR. WALLACE: Yeah.
 20 The one -- just a housekeeping issue.
 21 Dr. Guelcher --
 22 THE COURT: We have the jury monitors on. That's one
 23 of the reasons I wanted to have the defendants look at it, to
 24 be sure there's no objection before we go further.
 25 MR. WALLACE: Sure, thank you, Your Honor.

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1 THE COURT: So let's just hold for a second.
 2 MR. WALLACE: Sure.
 3 MR. THOMAS: Do you want me to review what's on the
 4 monitor, Your Honor?
 5 THE COURT: No, I asked them to go get the rest of
 6 them. I didn't realize there was going to be more than one.
 7 MR. THOMAS: Thank you.
 8 MR. WALLACE: We had a -- Your Honor, we just had a
 9 slight IT problem over lunch.
 10 THE COURT: Okay.
 11 MR. WALLACE: There's, apparently, the first-day
 12 jitters somehow infected the IT.
 13 THE COURT: There is a what?
 14 MR. WALLACE: We had some first-day jitters, I think,
 15 in the room outside where we're printing some things, and we
 16 weren't able to print. So I apologize, Your Honor.
 17 THE COURT: Well, you're apologizing to the right guy
 18 because I never have a problem with IT.
 19 (Laughter.)
 20 MR. WALLACE: I don't, either, Your Honor.
 21 THE COURT: If you can't print it, we'll -- could you
 22 take it over and show it to them?
 23 MR. WALLACE: Sure. And I will represent to -- I
 24 believe counsel has seen something like this previously, but
 25 I'll represent to you that the first three pages and perhaps

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1 the first 15 or so minutes is strictly going through the
 2 doctor's background, if that's okay with you.
 3 MR. THOMAS: That's fine.
 4 THE COURT: All right. Let's go ahead and proceed
 5 with it.
 6 MR. WALLACE: Thank you.
 7 BY MR. WALLACE:
 8 Q. So let's go back to that screen, Dr. Guelcher. I see a
 9 lot of what I call acronyms, DOD, AFIRM, et cetera. Can you
 10 just quickly walk through each of those and tell the jury what
 11 they mean and a little bit about the grant process?
 12 A. So, as a professor in the engineering school at
 13 Vanderbilt, one of my responsibilities is to write grant
 14 applications to federal agencies, to receive money to support
 15 the research that I use to pay students that I pay for
 16 materials. And these are a number of funding agencies. So
 17 the first, the NIH, is the National Institutes of Health.
 18 There is an institute that focuses on arthritis and
 19 bone diseases. I have funding from them.
 20 The NCI is the National Cancer Institute, and in
 21 these types of programs, we're interested in the problem of
 22 how does breast cancer damage bone, how does it metastasize in
 23 bone, why does that happen, how do we treat it?
 24 The last one is probably familiar to everyone. DOD
 25 is the Department of Defense, and the Department of Defense

1 has a very large program called Armed Forces Institute of
2 Regenerative Medicine, that's AFIRM, and that's a program that
3 involves about 20 universities and we're all working together
4 to find better treatments for soldiers that are injured in the
5 conflicts in Iraq and Afghanistan.

6 So, my primary contribution there is on bone grafts
7 to repair the mandible, so there's some very bad craniofacial
8 injuries. Survival rates are high in these wars, but soldiers
9 have devastating injuries that affect their quality of life.
10 So we're working to improve that through that program.

11 And the last one is the National Science Foundation,
12 which is -- has a very important education mission as well,
13 training grad students, so those are currently agencies that
14 I've applied for funding and have grants through them right
15 now.

16 Q. Do you have a particular area of research as it relates
17 to wound healing, Dr. Guelcher?

18 A. So, we are designing tissue grafts for healing skin, so
19 that would include things like diabetic foot ulcers. It would
20 also include problems with the wound vac, so you have a very
21 bad wound, they can put a vacuum on it to kind of clear it out
22 and help it heal better. We're working with a company to
23 design better foams for this procedure. So we work with a
24 number of wound-healing companies.

25 Q. Beyond the experience that you've described, you actually

1 worked at chemical companies before. Is that right?

2 A. That's right.

3 Q. Can you tell us a little bit about that?

4 A. So, right after college, I worked for Eastman Chemical
5 Company in Upper East Tennessee. There I was working on
6 polyesters, nutritional supplements such as vitamin E, vitamin
7 A.

8 After my Ph.D., I worked here in South Charleston, at
9 the Tech Center for about three years, so I was there when
10 Bayer had a facility at the Tech Center, as well as Dow. I
11 worked a lot with the South Charleston plant, just
12 trouble-shooting problems there, improving their processes,
13 and this was all polyurethane intermedia when I was at Bayer.

14 Q. Okay. Can you do me a favor? I just want to break that
15 up into two parts because you mentioned polyurethane. You
16 mentioned plant. You mentioned South Charleston. Could you
17 just take those one at a time for us?

18 A. Okay. So I started off at Bayer as a research engineer,
19 working in the polyurethanes division, and my responsibilities
20 there included designing new products that we would then
21 translate to the plant. So we would make some improvement in
22 the lab, and then we'd work with the plant to make sure that
23 they could do this in a cost-effective way. I did that for
24 about three years, until I left in 2003.

25 Q. From Charleston?

1 A. From South Charleston, yeah.

2 Q. And when you left South Charleston, West Virginia, where
3 did you go?

4 A. Then I went back to Pittsburgh for a post-doctoral
5 fellowship in biomedical engineering. That's when I shifted
6 fields somewhat.

7 Q. In addition to working for chemical companies as an
8 employee in your research, have you ever consulted with
9 medical device companies or other chemical companies?

10 A. Yes. So, I've done a fair amount of consulting work with
11 biomedical device companies, we're working with a -- a major
12 goal in my research is what we would call "translational."
13 So, that is, we try to discover things in the laboratory that
14 are new and then translate that to help people by making
15 better products. That's a very difficult thing to do because
16 universities do research and companies make products.

17 So, a lot of these I've been working on for some time,
18 but we work with the company to translate what we do in our
19 laboratory to make a product better, and then the company will
20 license this and then turn this into a commercial product. So
21 I have several projects like that going on right now. So, a
22 very keen interest of mine is innovation in the biomedical
23 device industry, is a very important thing to me. So...

24 Q. Have you worked in the field of polymers, Dr. Guelcher?

25 A. So, I've been working in polymers since I graduated from

1 college, even while I was in college, so working with
2 different types of materials, polyesters, polyurethanes, a
3 number of different polymers over 20-plus years.

4 Q. What is a polymer?

5 A. So, a polymer is -- you might think of it in terms of a
6 plastic, so you think about the seats that you're sitting on
7 right now, they have a polyurethane foam inside. That's what
8 makes it more comfortable than a slab of wood. Your mattress
9 has a polyurethane foam. So, essentially, it's a plastic
10 material that, many cases, is typically derived from oil
11 chemicals, petrochemicals, that -- and you start with a very
12 small molecule and you grow it into a long one, and then the
13 properties of these polymers are very important, yeah.

14 Q. Does the work that you've done in this case concern
15 polymers?

16 A. Yes. Specifically, an active area of my research is how
17 the body responds to polymers. If you place a polymer in the
18 body, what does it do? Do you want it to go away, do you want
19 it to be stable? So a lot of my work focuses on how cells and
20 tissues in the body respond to polymers. And I certainly
21 think that this case falls within the scope of that question.

22 MR. WALLACE: Your Honor, at this time, plaintiffs
23 would offer Dr. Guelcher as an expert in the field of chemical
24 engineering and biomaterials.

25 THE COURT: Any voir dire?

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1 MR. THOMAS: No, Your Honor.
 2 THE COURT: He may offer his opinions.
 3 MR. WALLACE: Thank you, Your Honor.
 4 BY MR. WALLACE:
 5 Q. Before we get to those opinions, Dr. Guelcher, have you
 6 been paid for the time that you've spent working on this case?
 7 A. Yes, I have been.
 8 Q. And how long have you been working on the issues of
 9 polypropylene mesh?
 10 A. I'd say at this point probably in the range of hundreds
 11 of hours. I spent a lot of time reading many scientific
 12 papers and documents.
 13 Q. Can you tell us just approximately how many scientific
 14 publications you've reviewed in the work that you've done in
 15 polypropylene, if you know?
 16 A. Probably exceeding 50, 60 papers, maybe more. There's a
 17 lot.
 18 MR. THOMAS: Your Honor, may we approach?
 19 THE COURT: You may.
 20 MR. THOMAS: Thank you.
 21 THE COURT: Ladies and gentlemen, I forgot to tell
 22 you, there will be occasions when we go to sidebar, just like
 23 we did earlier today. When we do, you're not supposed to hear
 24 what we're talking about so I turn on the sound machine, but I
 25 ask you to talk among yourselves and be your own sound

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1 machine.
 2 (The following occurred at sidebar.)
 3 THE COURT: All right. Mr. Thomas.
 4 MR. THOMAS: Thank you, Your Honor. Counsel, as the
 5 Court is aware, has tendered us a PowerPoint presentation of
 6 Dr. Guelcher's testimony.
 7 THE COURT: Um-hum.
 8 MR. THOMAS: Paragraph E is an opinion, more mesh
 9 equals more foreign body response, which is not contained in
 10 the summary of opinions in the expert report, and it's an
 11 opinion that goes beyond both his expert report and the
 12 depositions I took of Dr. Guelcher.
 13 MR. WALLACE: I would only add, Your Honor, that he
 14 filed a supplemental report shortly after that that addresses
 15 the more-mesh concept which is on Page 2 of his supplemental
 16 report --
 17 MR. THOMAS: I thought the supplemental --
 18 MR. WALLACE: -- which I will go get if you want me
 19 to.
 20 THE COURT: Let's see what he's got.
 21 MR. WALLACE: But I can tell you -- I will just wait.
 22 THE COURT: Wait.
 23 MR. WALLACE: Thank you, sir.
 24 MR. THOMAS: Your Honor, I brought the Court the
 25 supplemental report of Dr. Guelcher, and Page 2 of the

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1 supplemental report has exactly the same opinions that are in
 2 the original report.
 3 MR. WALLACE: No, there is a -- let me get you the
 4 right report, Dave. Let me go get the right report for him.
 5 THE COURT: Get whatever report you have.
 6 MR. WALLACE: More --
 7 THE COURT: That's all right. It was represented
 8 that he was not offering any new opinions on his supplemental
 9 report when I was considering Daubert motions.
 10 MR. WALLACE: Your Honor, this is a rebuttal report
 11 that was done many, many, many months ago, not the matter that
 12 you addressed. So --
 13 THE COURT: So it either was or wasn't in the report.
 14 MR. WALLACE: It is in the report, Your Honor. I can
 15 point it to you and point it to Dave, if you'd like me to.
 16 THE COURT: Why don't you two take a minute. I need
 17 to know the sequence --
 18 MR. WALLACE: Sure.
 19 THE COURT: -- because when I was ruling on the
 20 reports, as I recall, the -- the issue came up with regard to
 21 whether he was offering any new reports in supplement -- any
 22 new opinions in the supplement. And the answer I got from you
 23 all was "no."
 24 MR. WALLACE: And that is correct, Your Honor.
 25 THE COURT: All right. Why don't you all talk about

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1 it, whatever this is.
 2 MR. WALLACE: Sure.
 3 (Discussion held off the record between Mr. Wallace
 4 and Mr. Thomas.)
 5 THE COURT: Yes, sir.
 6 MR. THOMAS: Your Honor, I have spoken with
 7 Mr. Wallace, and Dr. Guelcher did, in fact, supply a rebuttal
 8 report to the expert reports of Ethicon. And we did file a
 9 motion, a Daubert motion -- let me back up. The rebuttal
 10 report does refer to Paragraph E, more mesh equals more
 11 foreign body response. We moved on Dr. Guelcher and the Court
 12 found in the order, I have the Daubert order if you'd like,
 13 and limited Dr. Guelcher to the four opinions in the original
 14 report --
 15 THE COURT: I don't remember a reference to a
 16 separate supplemental report. I remember -- give me that
 17 sheet of paper.
 18 MR. THOMAS: I have the Daubert order if the Court
 19 likes.
 20 THE COURT: Ethicon moved to exclude Dr. Guelcher's
 21 testimony as it relates to supplemental reliance material
 22 list. Did you go beyond that?
 23 MR. THOMAS: That's a different motion -- no, Your
 24 Honor. That was a motion -- they filed a supplemental
 25 reliance list adding new documents, right before trial, that I

<p style="text-align: right;">Page 94</p> <p>1 hadn't had an opportunity to depose Dr. Guelcher on.</p> <p>2 MR. WALLACE: Right.</p> <p>3 MR. THOMAS: The Court denied that motion because</p> <p>4 they were late-produced documents, as I recall the Court's</p> <p>5 order. What I'm referring to is the Daubert motion that we</p> <p>6 filed --</p> <p>7 THE COURT: Let me see a copy of the opinion that you</p> <p>8 are referring to.</p> <p>9 (Pause.)</p> <p>10 THE COURT: Show me. Show me where I limited</p> <p>11 Dr. Guelcher's opinion. I don't recall doing that.</p> <p>12 MR. THOMAS: Page 17 of the order, Your Honor.</p> <p>13 THE COURT: Where is it that you moved to limit his</p> <p>14 testimony about the opinion you're talking about?</p> <p>15 MR. THOMAS: The opinion that he's talking about</p> <p>16 here --</p> <p>17 THE COURT: Where is it that you moved to limit that?</p> <p>18 I don't remember that.</p> <p>19 MR. THOMAS: I understood that was part of the</p> <p>20 Daubert ruling, and the Court -- what I relied on is the Court</p> <p>21 specifically laid out what the opinions were going to be. The</p> <p>22 other alternative is this is not a true rebuttal opinion, but</p> <p>23 we can get to that later.</p> <p>24 THE COURT: What I'm trying to understand -- I'm</p> <p>25 sorry. Did you object and raise an issue, when -- in your</p>	<p style="text-align: right;">Page 96</p> <p>1 agreed, worked out the second deposition.</p> <p>2 This was months and months before the Daubert motions</p> <p>3 were ever filed, and so I would suggest that this opinion has</p> <p>4 been out there. It's nothing new.</p> <p>5 THE COURT: But it's not in his report.</p> <p>6 MR. WALLACE: It is in his report, Your Honor. It is</p> <p>7 in his expert rebuttal report that he filed which is the</p> <p>8 subject of the --</p> <p>9 THE COURT: Let's make it clear so the record is</p> <p>10 clear.</p> <p>11 MR. WALLACE: Thank you.</p> <p>12 THE COURT: What is the objection?</p> <p>13 MR. THOMAS: One, it's not in his original report.</p> <p>14 When we moved on Daubert grounds to strike his testimony</p> <p>15 entirely, for a number of reasons, the Court found these were</p> <p>16 the four opinions which he was to express at trial. That's</p> <p>17 what I --</p> <p>18 THE COURT: To be clear, are you saying that he did</p> <p>19 not offer this opinion before you made your motion?</p> <p>20 MR. THOMAS: No, I'm not, Your Honor.</p> <p>21 THE COURT: And did you move to say he wasn't</p> <p>22 qualified to offer this opinion?</p> <p>23 MR. THOMAS: I'm sure that I did, but I can't tell</p> <p>24 you specifically that I did, Your Honor.</p> <p>25 THE COURT: Well, I'll let the jury go take a break</p>
<p style="text-align: right;">Page 95</p> <p>1 Daubert motions in this particular opinion and his</p> <p>2 qualifications to offer it?</p> <p>3 MR. THOMAS: I'm hesitant to represent that, Your</p> <p>4 Honor, because it's been a long time since I looked at the</p> <p>5 actual papers, to be honest with you, so I can't represent</p> <p>6 that to the Court.</p> <p>7 MR. WALLACE: Your Honor?</p> <p>8 THE COURT: Yes.</p> <p>9 MR. WALLACE: Your Honor, you asked a question about</p> <p>10 the chronology, just so it's clear, and Mr. Thomas and I agree</p> <p>11 on this, this rebuttal report was offered before</p> <p>12 Dr. Guelcher's deposition was even taken the second time</p> <p>13 around. So we hope that it's a nonissue, we can move through</p> <p>14 quickly on the stand. In other words, he's been deposed. I</p> <p>15 just want --</p> <p>16 THE COURT: Was he cross-examined on that opinion?</p> <p>17 MR. WALLACE: Well, there was lots of hours of</p> <p>18 testimony by Mr. Thomas, from which Mr. Guelcher still --</p> <p>19 THE COURT: He didn't testify, did he? I'm teasing.</p> <p>20 (Laughter.)</p> <p>21 THE COURT: Go ahead and finish your thought.</p> <p>22 MR. WALLACE: No, I was just saying, Your Honor, and</p> <p>23 Mr. Thomas agrees with this, we provided this rebuttal report,</p> <p>24 Mr. Thomas and I agreed that even Mr. Guelcher can come back</p> <p>25 and be deposed a second time, and Mr. Thomas and I mutually</p>	<p style="text-align: right;">Page 97</p> <p>1 and you show me what you did.</p> <p>2 MR. THOMAS: I'm not going to be able to put my hands</p> <p>3 on it very quickly and I'm reluctant to take that much time</p> <p>4 with the jury. I don't want to do that to the Court or --</p> <p>5 MR. WALLACE: Dave, can I offer a suggestion?</p> <p>6 MR. THOMAS: Sure.</p> <p>7 THE COURT: Off the record.</p> <p>8 (Discussion held off the record between Mr. Wallace</p> <p>9 and Mr. Thomas.)</p> <p>10 MR. THOMAS: Your Honor, I think we have reached an</p> <p>11 accommodation on it.</p> <p>12 THE COURT: Okay. Let's go.</p> <p>13 (Sidebar concluded.)</p> <p>14 THE COURT: Okay. Mr. Wallace?</p> <p>15 MR. WALLACE: Can we move to the next slide. Let's</p> <p>16 just go ahead and try to move ahead a little.</p> <p>17 BY MR. WALLACE:</p> <p>18 Q. Did you provide an expert report, a rebuttal report and</p> <p>19 some reliance lists in this case?</p> <p>20 A. Yes, I did.</p> <p>21 Q. Okay. And in those documents, did you provide certain</p> <p>22 opinions?</p> <p>23 A. Yes, I did.</p> <p>24 Q. Okay. And would you agree with me that the reports that</p> <p>25 you filed and the rebuttal report you filed were much more</p>

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1 extensive than what we have here represented on the slide?

2 A. Yes.

3 Q. Okay. Well, just to move forward, is this your summary

4 of opinions?

5 A. This is my summary of opinions.

6 Q. Okay. And, Dr. Guelcher, before we get to the summary of

7 your opinions, what I want to do is just establish some

8 definitions for the jury.

9 And I'm going to start with, Dr. Guelcher, what is

10 polypropylene?

11 A. So, polypropylene is a manmade or a synthetic material,

12 in a chemical plant. It's based on a petrochemical, and it's

13 produced in pellet form as shown in the picture there. And an

14 important point about this is that polypropylene is known to

15 be unstable, due to its molecular structure, the reactive

16 oxygen, and so, like many other products, antioxidants are

17 added to extend the service life of the polypropylene, to make

18 it last longer for the application it's designed for. That's

19 the purpose of the antioxidants.

20 Q. Can you tell the jury what -- some products that are made

21 with polypropylene?

22 A. Well, polypropylene parts are important in automotive

23 applications, toys, fishing line. It's a very well-known

24 industrial chemical that's used in a lot of applications.

25 Q. Let's go back to your summary opinion slide,

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1 Dr. Guelcher. It says, "Polypropylene plus oxygen equals

2 degradation." What do you mean by that?

3 A. So, polypropylene will react with oxygen and degrade.

4 This is known as an oxidation reaction. And that changes the

5 chemical structure of the polypropylene, is the most important

6 point. So, by reacting with the oxygen, its chemical

7 structure is changed. It's not stable.

8 Q. And I first want to talk about polypropylene outside of

9 the body.

10 A. Yes.

11 Q. Okay? So, when you're talking about polypropylene

12 reacting with oxygen equalling degradation, are you referring

13 to polypropylene outside of the body?

14 MR. THOMAS: Your Honor, objection, leading.

15 THE COURT: Sustained, but you can ask it directly

16 pretty easy.

17 BY MR. WALLACE:

18 Q. What happens to polypropylene out of the body?

19 A. Outside of the body, polypropylene can react with oxygen,

20 molecular oxygen just in the air that we breathe, O₂. This is

21 a faster reaction rate at higher temperatures, so in order to

22 make polypropylene useful, we saw the pellets. A pellet's not

23 very useful. So what you'll do is you'll heat it up and

24 either extrude it or mold it, but you have to heat it to high

25 temperatures in order to process it into a useful part. And

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1 these oxidation reactions can become very important at those

2 conditions.

3 Q. Let's just try to march through these, and then maybe

4 we'll come back to a few of them.

5 Number -- I'm sorry, Letter B, it says, "Antioxidants

6 can slow down degradation, but they cannot prevent it." What

7 do you mean by that?

8 A. So, this relates to the concept of a service life. So,

9 just about anything that you make or buy has a -- it's useful

10 for a certain period of time. Then it wears out. And the

11 same applies to plastics. And so antioxidants can slow this

12 degradation process, these chemical changes, for a period of

13 time, they can extend the service life, but they can't prevent

14 it forever. This process will continue, and eventually these

15 changes will happen. The question is when.

16 Q. When you talk about changes, are you talking about the

17 degradation process?

18 A. Yes. Changes to the structure of the molecule, of the

19 polypropylene.

20 Q. How long has this been known in the chemical field,

21 Dr. Guelcher?

22 A. Since the 1960s. When polyurethane -- polypropylene was

23 first invented, it was noticed that it had these degradation

24 problems, and that's when scientists started adding

25 antioxidants to make it last longer.

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1 Q. Let's move on to C. It says, "The body's natural defense

2 mechanism -- the foreign body response -- attacks the

3 polypropylene."

4 Let's take those one at a time. Dr. Guelcher, what are

5 you referring to when you say "the body's natural defense

6 mechanism"?

7 A. So, this is the response that your body has when a

8 foreign material is implanted, the material that your body

9 knows is not part of your body, and there's a defense

10 mechanism that the body has to deal with this to reject it or

11 to destroy it, and this is essentially the natural defense

12 mechanism.

13 Q. What do you mean by -- could you give us an explanation

14 of "foreign body response," or is that what you just --

15 A. So, the foreign body response or the foreign-body

16 reaction is a scientific term that's used to explain this

17 defense mechanism. So, there's a reaction that happens when a

18 foreign body is implanted at the cellular level, so this

19 happens actually to specific cells that attack the material.

20 That's what I'm referring to by the foreign body reaction.

21 It's just this natural defense mechanism.

22 Q. Dr. Guelcher, "attack" seems like a pretty strong word,

23 so could you explain that to the jury?

24 A. So, cells in your body, known as inflammatory cells,

25 these would be things like white blood cells, macrophages,

1 foreign-body giant cells, these are inflammatory cells that
2 their job is to attack the foreign body.

3 A simple example would be a bacterial infection.
4 Bacteria is not supposed to be there, and so there's
5 specialized cells in the body that attack that and try to
6 destroy it so it doesn't harm the body. That's the response.

7 Q. Letter D says, "The foreign body response will not stop
8 until the mesh is removed." Do you see that?

9 A. Yes.

10 Q. And what do you mean by it?

11 A. So, the mesh is a foreign body. It -- it's not naturally
12 in your body. Like I said, it's a synthetic polymer that's
13 made in a chemical plant. It's planted in the body to
14 accomplish a certain purpose. And the body recognizes it as a
15 foreign material, and it will continue to attack it in this
16 way until it's removed or destroyed or it's gone.

17 Think of a splinter that you get in your finger. If
18 you never remove it, it over time will extrude. It's a simple
19 example, but that's the idea. It's ongoing until the foreign
20 body is gone.

21 Q. And you use the word "mesh." What are you referring to?

22 A. I'm referring to the polypropylene Prolene mesh that
23 we're discussing here today.

24 Q. When you say, "More mesh equals more foreign body
25 response," what do you mean?

1 A. So, this is sort of a logical consequence of the other
2 opinions, in that if you have more mesh present -- this is
3 happening at the surface of the material, at the surface is
4 where it's happening. If you have more mesh, well, you're
5 going to have more response. It's going to be an elevated
6 response. More cells, more reactive oxygen, more -- it's an
7 elevated response, yeah.

8 Q. Well, you talked about more reactive oxygen and gave a
9 couple of other words that I think we're going to need to
10 define.

11 A. Yes.

12 Q. But why don't we try to go, just keeping moving through
13 it, and we'll come back to that.

14 Next slide. Keep going. Okay. What -- first of all,
15 before we get into the structure here, what are you trying to
16 explain to the jury?

17 A. So, this slide is explaining how this reaction that's
18 known as oxidation -- oxidation is a reaction with oxygen --
19 how this oxidation reaction alters the structure of
20 polypropylene. So you start off with the structure of
21 polypropylene, and you end up with something that's different.
22 That's the purpose of this slide.

23 Q. And so on the left, does that represent the chemical --

24 A. So --

25 Q. Let me -- excuse me, Doctor.

1 A. I'm sorry.

2 Q. I'm sorry, let me finish.

3 Let me ask it this way: What is the box on the left?

4 A. Okay. So the molecule on the left is the structure of
5 polypropylene. That's a unit that repeats, so it's a very
6 long chain of these units. And the box in red, that's the
7 carbon-hydrogen tertiary bond. Why is it a tertiary bond?
8 Well, that carbon is bonded to other carbons, except for that
9 hydrogen. That's why it's a carbon-hydrogen tertiary bond.
10 So this is kind of the chemistry concept.

11 So -- and that bond is vulnerable to attack by the
12 oxygen. That's where the attack is happening. And there is a
13 series of reactions in this step that lead to changes in the
14 polypropylene structure, but that particular bond is the one
15 that reacts.

16 THE COURT: Hold just a second. It's not usual, just
17 so the jury knows, it's not usual for me to be showing you
18 things on here that the witness hasn't first tried to explain
19 or -- and I have a series of slides, it appears.

20 Have you had an opportunity to review them?

21 MR. THOMAS: I'm looking at them right now, Your
22 Honor.

23 THE COURT: What I want -- what I want to do is not
24 put them up until I see if there's an objection.

25 MR. WALLACE: Sure, Your Honor. I didn't realize --

1 THE COURT: So before you get ready to go to your
2 next one, we'll see it.

3 MR. THOMAS: I have no objection to the next one,
4 Your Honor.

5 THE COURT: All right.

6 MR. WALLACE: Okay.

7 THE COURT: If we could just keep that process up, I
8 would appreciate it.

9 MR. WALLACE: And going forward, that will absolutely
10 be the case, Your Honor.

11 THE COURT: Thank you.

12 BY MR. WALLACE:

13 Q. When you said "vulnerable to attack," can you just tell
14 the jury what concept you're trying to explain?

15 A. There's a reaction between the oxygen and that bond.

16 Q. What's the next red box represent?

17 A. So, the next red box shows how that bond changes, so you
18 start off with this tertiary carbon-hydrogen bond. The next
19 red box shows that bond turn into what's called a
20 hydroperoxide bond, so it changes. Its chemical structure
21 changes. That's what's denoted there.

22 Q. When you say "chemical structure changes," you're saying
23 that the polypropylene actually changes because of oxidation
24 or something else?

25 A. Yes. It's a different molecule now, because you have

1 this hydroperoxide group instead of the hydrogen that's
 2 changed.
 3 Q. And we talked a little bit about antioxidants already.
 4 But why don't we look at that second bullet point, where it
 5 refers to structural changes. Can you tell the jury what
 6 you're trying to say there?
 7 A. So, these changes in the structure, for example, the
 8 carbon-hydrogen bond going to a hydroperoxide bond, that could
 9 be measured using analytical techniques such as spectroscopy,
 10 so we could measure that, we can measure that change, and we
 11 can also measure the change in the following reaction when it
 12 goes to a carbonyl, which is the last red box. That's another
 13 chemical change that we can measure by different analytical
 14 changes.
 15 Q. When you say "we," who are you referring to?
 16 A. Scientists, engineers.
 17 MR. WALLACE: Let's go to the next slide, please.
 18 MR. THOMAS: That's fine.
 19 MR. WALLACE: Okay. Thank you.
 20 BY MR. WALLACE:
 21 Q. You say at the top, "Implant materials selection." And
 22 at the top you have "polypropylene," and then you have an
 23 arrow. What do you mean?
 24 A. So, this slide is showing several different types of
 25 materials, and how easily they are oxidized or how easily this

1 reaction with oxygen can occur. And so at the bottom, where
 2 it says, "Difficult to oxidize," these are materials that
 3 react very slowly with oxygen. For example, Teflon, Teflon
 4 reacts slowly with oxygen.
 5 Polypropylene, on the other hand, is one of the more
 6 easily oxidized materials. So it's reacting much faster with
 7 oxygen than a large number of other materials. It's much more
 8 easily oxidized in that respect.
 9 Q. How long have chemical scientists like yourself known
 10 that polypropylene is easily oxidized?
 11 A. This has been known for decades, I think. Since the
 12 1960s, it was known that polypropylene is easily oxidized.
 13 MR. WALLACE: Can you go to the next slide, please.
 14 Dave --
 15 MR. THOMAS: That's fine.
 16 MR. WALLACE: Thank you.
 17 BY MR. WALLACE:
 18 Q. All right. You've talked a little bit about foreign body
 19 reaction. You've got some photos here. Can you take us
 20 through them?
 21 A. So I mentioned the foreign-body reaction earlier. This
 22 is the body's response to something that's implanted. It's
 23 caused -- it's called the foreign-body reaction because that
 24 refers specifically to the types of cells that respond. So
 25 it's a reaction. You implant the material, and certain cells

1 respond.
 2 And so these are polyurethane films that were in the
 3 body, and it shows the progression of this reaction. So in
 4 the upper left-hand corner it says, "Monocytes, zero days," so
 5 very quickly after an implantation of the device, or this
 6 material, this foreign body, monocytes, which are very small
 7 mononuclear cells, they have one nucleus, they attach to the
 8 surface. They recognize it as a foreign body and they attach.
 9 And that's what starts off this reaction.
 10 Now, as you see the arrow there, it points to
 11 macrophages at three days. Then these monocytes over a period
 12 of several days change to form another cell called
 13 "macrophage." And it's important to remember these cells are
 14 attached to the surface. They're what we call an adherent
 15 cell. They're attached to the surface of the material.
 16 And then after about a week, some of these macrophages
 17 will fuse. That means they join together to form a great big
 18 cell that has multiple nuclei instead of just one, and then
 19 finally, after about two weeks, that FBGC 14 days, those are
 20 called foreign-body giant cells. That's just what they are,
 21 they're giant cells, they're very large cells that have
 22 multiple nuclei. And, again, all these cells are adherent to
 23 the surface.
 24 So, what happens at the surface is they're secreting
 25 what's known as reactive oxygen species. And this is oxygen

1 that's -- these are oxygen species that are much more reactive
 2 than molecular oxygen, so they're much more potent. They
 3 react faster. And that material surface is exposed to these
 4 species. So it's exposed to these oxidizing agents.
 5 This is what's known as the foreign-body reaction. But
 6 it's driven by these types of cells that attach to the surface
 7 and secrete reactive oxygen species with an aim to destroy the
 8 material. That's why they're there. They want to remove this
 9 material because it's a foreign body.
 10 Q. Okay. So, if I understand you correctly, the monocytes
 11 work with the macrophages to combine the foreign-body giant
 12 cells and adhere to the surface of a foreign body; is that
 13 right?
 14 A. Yes, they're adherent, yes.
 15 Q. All right. Going back to this "attack" word that you
 16 used, is that what you're describing there?
 17 A. This is the scientific explanation of the word "attack."
 18 It's a chemical attack. It's, again, reactive oxygen species
 19 or ROS.
 20 Q. What are the -- what are these foreign-body giant cells
 21 actually trying to do to the implant?
 22 A. Well, they're trying to remove it from the body. That's
 23 the response, to destroy it.
 24 Q. What does ROS do in the body? What function does it
 25 serve?

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1 A. So, much like if you take polypropylene and you heat it
2 in the air, your source of oxygen in the air is molecular
3 oxygen that we breathe, so if you heat it up, that molecular
4 oxygen in the air will react.

5 Well, in the body, it's a much lower temperature. So
6 you don't have this thermal oxidation, at high temperatures,
7 but the reactive oxygen species serves the same purpose.
8 They're much more reactive than oxygen at the body conditions,
9 and so they can cause these changes to polypropylene because
10 of their high reactivity.

11 Q. Dr. Guelcher, if I heard you correctly, are you offering
12 an opinion that reactive oxidative species is actually --
13 has -- is stronger than the oxygen --

14 MR. THOMAS: (Stands.)

15 THE COURT: Sustained.

16 BY MR. WALLACE:

17 Q. What effect -- let me ask this question: Does ROS have
18 an effect on polypropylene implanted in the human body?

19 A. Yes, it does, because polypropylene reacts with oxygen.
20 This is simply a much more potent form of oxygen, so it's a
21 similar reaction.

22 Q. Thank you.

23 And how long has the foreign-body reaction been
24 understood by scientists and biomedical engineers like
25 yourself?

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1 designing a material, is: How is the material that I'm
2 implanting going to respond to that foreign body reaction?
3 That's something I can control, as an engineer, and it's a
4 very important question.

5 So, here I'm using the example of the
6 poly(ether)urethane pacemaker lead to explain this point.

7 And so these were, again, materials that were believed
8 to be safe, and then some patients started having problems and
9 the leads were taken out of the body or explanted, and some
10 studies were done, and it was shown that the combination of
11 chemical degradation that results from the foreign-body
12 reaction, that's the reactive oxygen, causes chemical
13 degradation, just like I explained for polypropylene. That
14 combined with physical damage such as cracking, in response to
15 this, embrittlement, led to device failure in a number of
16 patients, so it can be a very serious problem. And it doesn't
17 stop until the device is removed. And this has led to the
18 discovery of replacing materials for this application.

19 So, in this little chart here, I tried to show what I
20 consider to be really a vicious cycle of this problem. So if
21 you look at the bottom, when the device is implanted, you have
22 this infiltration of inflammatory cells, that's at the bottom.
23 And that happens once the device is implanted. So you get
24 these cells that attach to the surface, and then oxidation,
25 that's in response to the reactive oxygen secreted by the

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1 A. So, this was discovered in the early 1990s in a few very
2 important papers. It was discovered that the failure of
3 certain biomaterials could be traced in this foreign-body
4 reaction. So materials that were thought to be safe, such as
5 insulation and cardiac pacemaker leads, thought to be safe,
6 but in the early 1990s, we realized that, in fact, it wasn't
7 because this foreign-body reaction was causing it to degrade.
8 That's what -- so it was in the early '90s.

9 MR. THOMAS: This is the polyurethane slide?

10 MR. WALLACE: Okay.

11 MR. THOMAS: Yes.

12 MR. WALLACE: Okay. We'll just go to the next slide.

13 BY MR. WALLACE:

14 Q. Can you describe to the jury what you have done with this
15 slide? And can I withdraw the question and ask you a
16 different one?

17 Did you actually create this slide yourself?

18 A. Yes, I did.

19 Q. Okay. So, tell the jury what you're trying to explain
20 there.

21 A. So, I spent some time talking about the foreign-body
22 reaction. And this happens no matter what you implant. Even
23 it can happen with other types of dead tissue. It -- it
24 happens with anything you implant into the body.

25 The important question as an engineer, someone

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1 cells.

2 So, now we have oxidation of the material or reaction,
3 it's changing, it becomes embrittled. This can result in loss
4 of flexibility, cracking, which leads to more exposed surface.
5 So this reaction starts at the surface and it keeps going down
6 into the bulk of the material, can result in mechanical
7 failure. So this is the effect that the foreign-body reaction
8 can have on an implant that's not resistant, that's not --
9 that is susceptible to reaction with oxygen. That's what's
10 summarized in this slide.

11 Q. Dr. Guelcher, have you -- are you aware of any instance
12 where degradation might be desired in an implant?

13 A. So, in my own research at Vanderbilt, these are some
14 papers we published just in the past few years. And we're
15 interested in a different problem, that is, if I have a bone
16 void and it's not healing, can I put a scaffold in there or a
17 graft that will help it to heal. In other words, it won't
18 heal because there is a large hole, but if I put a structure
19 that has a scaffold to it, cells can migrate in and heal it.

20 Now, in this application, we want that scaffold to go
21 away once the wound is healed, but it's very important that we
22 control the rate at which it goes away. So we've actually
23 designed materials that respond to this foreign-body reaction,
24 in other words, they are designed to go away once cells start
25 to cause a new matrix, they degrade the scaffold, and the end

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1 result of this process is you have a healed wound.

2 So we're actually using this foreign-body reaction to
3 design new materials that will improve healing. That's quite
4 different from the polypropylene case where you want it to be
5 stable. That's a very different application. But my point is
6 that we can -- as an engineer, we can actually design
7 materials that respond to this foreign-body reaction, to
8 accomplish healing. That's the work that I'm doing now.

9 Q. I want to make sure I've heard you correctly, going back
10 to whether or not the process ever stops. Is there any time
11 that the reactive oxidative species will stop attacking the
12 mesh?

13 MR. THOMAS: Asked and answered, Your Honor.

14 THE COURT: Sustained.

15 BY MR. WALLACE:

16 Q. Does polypropylene degrade inside the human body?

17 A. Yes, it does.

18 Q. Can you explain that to the jury?

19 A. It's the same process of attachment of inflammatory cells
20 that then secrete reactive oxygen, the polypropylene reacts
21 with that oxygen, and the composition changes.

22 Q. When you use the word "embrittlement," what do you mean?

23 A. So, "embrittlement" is a technical term that refers to
24 the transition from a plastic that starts off being very
25 compliant or stretchy, you can pull on it like a rubber band,

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1 while it's being processed at high temperatures. So you have
2 a pellet, and you want to make something useful out of the
3 pellet. You have to heat it up and remold it. This requires
4 high temperatures, and so these antioxidants are designed to
5 protect while it's being processed at high temperatures, and
6 some of them are expended, at this time. They're consumed,
7 they're used up.

8 Now, a secondary oxidant essentially enhances the
9 primary one. It's intended to improve long-term storage.
10 It's intended to protect against ultraviolet light. So
11 different antioxidants do different things and they're used in
12 combinations that have an overall good effect to stabilize it.

13 Q. Why is that important to you, as an expert in biomedical
14 and chemical engineering in this case?

15 A. Well, the question that I would have is these
16 antioxidants are designed to protect during processing and
17 during long-term use, exposure for several years to summers in
18 Tennessee, for example, but they're not optimized to protect
19 polypropylene against this reactive oxygen in vivo.

20 Q. Dr. Guelcher, can I interrupt you there?

21 A. Yes.

22 Q. What do you mean by that?

23 A. Well, they are not designed or they not intended to
24 protect polypropylene against this reactive oxygen, against
25 this foreign-body reaction.

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1 and it becomes more brittle, so it's -- then it's like a hard,
2 rigid plastic. It's hard, it's rigid, it cracks. That's what
3 we mean by "embrittlement."

4 Q. Do you have an opinion on whether polypropylene becomes
5 embrittled inside the human body?

6 A. Yes. So, the consequence of this response to the
7 foreign-body reaction is embrittlement. That's one
8 consequence, that's one response.

9 Q. Do you have an opinion on whether polypropylene suffers
10 from a loss of flexibility inside the human body as a result
11 of embrittlement?

12 A. Yes. So, loss of flexibility would happen when it
13 becomes brittle. It's no longer compliant or stretchable.

14 Q. We talked earlier about antioxidants.

15 MR. WALLACE: Can we go to the next slide?

16 MR. THOMAS: Yes.

17 BY MR. WALLACE:

18 Q. Can you explain to the jury the reason for this slide?

19 A. So, as I mentioned before, because of the susceptibility
20 of reactivity of polypropylene with oxygen, we have to add
21 antioxidants. And these are typically packaged as primary and
22 secondary antioxidants, and this technology, again, was worked
23 out largely in the 1960s.

24 So, what do I mean by "primary" and "secondary"? Well,
25 a primary antioxidant is one that is intended to protect it

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1 Q. What do you mean by "intended"?

2 MR. THOMAS: Objection, Your Honor, testifying to the
3 state of mind of Ethicon.

4 MR. WALLACE: I'm not talking about Ethicon, Your
5 Honor. I'm asking --

6 THE COURT: Overruled. Go ahead.

7 THE WITNESS: So the purpose of the antioxidant is to
8 protect against processing at thermal -- sorry -- processing
9 at higher temperatures, long-term exposure to atmospheric
10 oxygen that we breathe. Its purpose is not to protect against
11 reactive oxygen in vivo. It's not possible because the
12 reactive oxygen, foreign-body reaction, wasn't discovered
13 until 1990.

14 So these antioxidant packages, when they were
15 created, they simply didn't know about the foreign-body
16 reaction, so this wasn't taken into account when they were
17 designed.

18 BY MR. WALLACE:

19 Q. Do you know whether or not -- well, why is that important
20 to the TVT-O device?

21 A. Well, because it's -- it's not guaranteed that these
22 antioxidants are going to protect against the reactive oxygen
23 in the body. It's not been studied. It wasn't looked at. It
24 wasn't taken into account when these devices were designed.

25 Q. Do you know whether or not the Prolene mesh that is the

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1 TVT-O mesh, do you know whether or not that has an antioxidant
 2 package added to it?
 3 A. So, Prolene has this package of secondary anti- --
 4 primary and secondary antioxidants. It has a primary
 5 antioxidant, this is what's referred to as a hindered phenolic
 6 compound. What that means is it reacts with free radicals,
 7 and it doesn't evaporate when you heat it to high
 8 temperatures, it stays in the material, it doesn't evaporate
 9 into the air.

10 It also has a secondary antioxidant which is a typical
 11 one that's used. This is a thioester and, again, this is
 12 intended to improve long-term storage at atmospheric
 13 conditions, not in the body, but atmospheric conditions.
 14 Q. Do you have an opinion on whether the antioxidant package
 15 that is added to the Prolene mesh that is the TVT-O stops
 16 degradation?

17 MR. THOMAS: Objection, Your Honor. Sidebar, please.

18 THE COURT: Hold just one second.

19 All right. Let's see you at sidebar.

20 (The following occurred at sidebar.)

21 MR. THOMAS: Your Honor, Ethicon objects to the
 22 question as phrased because not only is it an opinion that is
 23 not expressed in the four, now five, which he's been permitted
 24 to testify, but he has not done any testing and analysis with
 25 respect to Prolene specifically to give an opinion about the

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1 extent to which the antioxidants in Prolene would deplete over
 2 time and lead to degradation.

3 MR. WALLACE: Your Honor, if I were to respond, I
 4 would say it would be comprised within Opinion 1, and
 5 Mr. Guelcher, as I understand it, has been extensively
 6 questioned by Mr. Thomas on the antioxidant issue here in
 7 connection with his opinion about 1.

8 THE COURT: Excuse me.

9 (Pause.)

10 THE COURT: It is not listed precisely, but it was
 11 explained by you and included in the opinion. There was an
 12 extensive explanation about the evidence. What's your point?
 13 I'm sorry.

14 MR. THOMAS: I'm trying to understand the ruling.
 15 The witness has not done any testing to determine the extent
 16 to which the antioxidants may deplete over time.

17 THE COURT: He has not and he is not --

18 MR. THOMAS: (Indicating.)

19 THE COURT: Don't shush me.

20 MR. THOMAS: I'm sorry. That's a mannerism, not a
 21 shush. I apologize.

22 THE COURT: He has not. I didn't understand the
 23 question to be, had he done testing. Was that the question?

24 MR. THOMAS: That's the objection, to him giving that
 25 opinion as phrased because there is no basis in science or no

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1 testing to say, to a reasonable degree of certainty, that the
 2 Prolene, polypropylene mesh, leaches antioxidants or depletes
 3 antioxidants over time so it would degrade.

4 THE COURT: I'm going to allow him to testify and be
 5 subject to cross-examination.

6 MR. WALLACE: Thank you, Judge.

7 (Sidebar concluded.)

8 BY MR. WALLACE:

9 Q. Dr. Guelcher, with the indulgence of counsel, I just want
 10 to go back and reorient us to where we were. We were talking
 11 about the polypropylene antioxidants that are added during the
 12 manufacturing process to the Prolene mesh. Is that correct?

13 A. That's right.

14 Q. Okay. And, just to get us back to where we were, you
 15 said that, if I'm correct, you had an opinion on whether or
 16 not those antioxidants that are added to the Prolene mesh
 17 stopped the mesh from degrading. Is that right?

18 A. Yes.

19 Q. Okay. Can you explain why it is, why is it your opinion
 20 that the antioxidant package that's added to the Prolene mesh,
 21 that is ultimately made into the TVT-O, does not stop
 22 degradation?

23 A. Well, I've seen evidence that Prolene sutures undergo
 24 this reaction with oxygen and showed evidence of surface
 25 cracking. Based on that evidence that I've seen, I don't

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1 believe these antioxidant packages stabilize polypropylene
 2 against ROS in vivo, in the body.

3 Q. And what specifically -- what evidence are you
 4 specifically referring to?

5 A. There were -- there are two studies that I've reviewed.
 6 One was a study in dogs where these sutures were followed up
 7 to seven years, and the other is studies of sutures that were
 8 explanted from human patients for up to eight years. That's
 9 the evidence.

10 MR. WALLACE: 2026, Dave.

11 MR. THOMAS: Do you have a copy for me?

12 MR. WALLACE: I'm sorry.

13 MR. THOMAS: Thank you.

14 MR. WALLACE: Your Honor, I was able to talk to
 15 Mr. Thomas during the break about the four documents we'll be
 16 referencing.

17 THE COURT: Yes.

18 BY MR. WALLACE:

19 Q. So, Dr. Guelcher, you've -- do you have Exhibit 2026 in
 20 front of you?

21 A. Yes.

22 Q. Okay.

23 MR. WALLACE: Dave -- I'm sorry, counsel, do you have
 24 it?

25 MR. THOMAS: I do, thank you.

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1 MR. WALLACE: Okay.

2 BY MR. WALLACE:

3 Q. Is this one of the studies that you're referring to?

4 A. Yes.

5 MR. WALLACE: Your Honor, may I publish it on the

6 screen?

7 THE COURT: Do you want to move its admission?

8 MR. WALLACE: Well --

9 MR. THOMAS: I have no objection, Your Honor.

10 THE COURT: It may be received.

11 MR. WALLACE: Thank you, Your Honor.

12 (PLAINTIFFS' EXHIBIT P-2026 WAS RECEIVED IN EVIDENCE.)

13 THE COURT: Make sure that the paper copy is provided

14 to the Courtroom Deputy -- after. You don't have to do it

15 this minute. But just be sure.

16 MR. WALLACE: Thank you.

17 BY MR. WALLACE:

18 Q. And what is in front of you, Dr. Guelcher?

19 A. So, this is a document explaining the analysis of Prolene

20 sutures that were explanted from humans.

21 Q. And if you look at the top of the left-hand page, where

22 it says, "IR microscopy of explanted Prolene." Do you see

23 that?

24 A. Yes.

25 Q. In your review of this study, what does that mean to you?

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1 A. So, IR is infrared, spectroscopy, and infrared

2 spectroscopy is useful for identifying specific chemical bonds

3 in the material, so it tells us what bonds are there. And

4 this is a spectroscopy technique that's used to assess that.

5 Q. And do you know whether or not this is an Ethicon study?

6 A. Yes, it has Ethicon letterhead on it, so this was --

7 Q. And do you -- do you know the date that this document was

8 published?

9 A. So it's September 30th, 1987.

10 MR. WALLACE: Can you pull that up and also the

11 "Samples" paragraph at the top?

12 BY MR. WALLACE:

13 Q. When you said that it was a human -- that it came from a

14 human, if you can look at that language and explain to the

15 jury what they're seeing.

16 A. So, this is a human vascular graft, that's a blood vessel

17 graft, that was explanted -- that means it was taken out of a

18 human -- by this Professor Guidoin in Quebec, I believe, and

19 examined by IR spectroscopy.

20 Q. And if you could go to Page 2 and look at the

21 conclusions, please.

22 Tell us, Dr. Guelcher, what you found significant about

23 the conclusions in this Ethicon study.

24 A. So, the first conclusion states that the amount of DLTDP,

25 that's a secondary antioxidant -- that's the secondary

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1 antioxidant that's used in Prolene -- is reduced in the

2 explanted sutures. So no DLTDP is observed in the surface

3 scrapes, so there were cracks on these regions that they

4 scraped. They didn't see --

5 Q. Can we stop there for a second --

6 A. Yes.

7 Q. -- so we can take it one step at a time, Dr. Guelcher.

8 When you say "DLTDP," are you referring to the

9 antioxidant?

10 A. Yes, that's the antioxidant.

11 Q. And can you explain in practical terms what the

12 significance of this conclusion is as it relates to your

13 opinions?

14 A. Well, the way I interpret this statement is there are

15 cracked regions, so, again, this foreign-body reaction can

16 lead to cracking, embrittlement, because brittle things crack.

17 These cracked regions show no evidence of this stabilizer, so

18 that means that the stabilizer is expended, it was used. It

19 was used up in this region. And once it's used up, there's

20 nothing to protect the polypropylene from reacting. So it

21 tells me that the antioxidant in this cracked region was

22 consumed and that the polypropylene had oxidized. This is

23 what this tells me.

24 THE COURT: May I interrupt just a second? This is

25 1987. I thought you said they didn't figure this out until

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1 the '90s.

2 THE WITNESS: Well, sir, I meant that the

3 foreign-body reaction wasn't discovered until the '90s, but

4 this was an observation that was made independent of that

5 discovery.

6 THE COURT: What's the difference?

7 THE WITNESS: Well, so the discovery in 1990 was why

8 this happens. So there were a number of observations in the

9 '70s and '80s that this was happening. And it wasn't until

10 the 1990s where it was explained on sort of a cell and

11 molecular level what exactly was happening. This is an

12 observation.

13 THE COURT: Proceed.

14 MR. WALLACE: Thank you, Your Honor.

15 BY MR. WALLACE:

16 Q. With respect to Conclusion Number 2, what is the

17 significance of Conclusion Number 2 to your opinion of -- on

18 whether or not the antioxidants stop the degradation process?

19 A. Well, I think Number 2 is consistent with Number 1, in

20 that these cracks cannot be attributed to protein or tissue

21 that's sticking to the material. It's not material from the

22 body. It's cracked polypropylene, oxidized polypropylene. So

23 this is consistent with the notion that the antioxidant was

24 consumed and the polypropylene had reacted.

25 Q. What -- with respect to the word "protein" in these kinds

Page 126

1 of studies, what are they referring to?

2 A. Well, protein would be -- it's a component of tissue. So

3 tissue from the body, this is essentially, in my

4 interpretation, saying that there's no tissue that's stuck to

5 these sutures. It was successfully cleaned, and what you're

6 looking at is the polypropylene. You're not looking at tissue

7 that's stuck.

8 Q. Thank you.

9 Can we just move to 3 then, please.

10 What's the significance of Conclusion Number 3 to your

11 opinion, Dr. Guelcher?

12 A. So, Statement Number 3 is again saying there are these

13 cracked regions of the suture, where we see cracking, that was

14 scraped off, and that scraped-off material that had cracked,

15 they did an experiment to measure at what temperature does it

16 melt. So we know that pure polypropylene melts at a certain

17 temperature, and this material melted at a temperature below

18 that, so that's a change in the melting temperature. That

19 tells us there's a change in the polypropylene because pure

20 polypropylene melts at a specific temperature just like, you

21 know, ice melts at zero degrees, you know, zero degrees

22 Celsius. Ice melts at a defined temperature.

23 In the same sense, polypropylene melts at a very

24 defined temperature as determined by the structure, and if

25 that structure changes, the melting temperature will change,

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1 and that's what was seen here. So there's a change in the

2 melting temperature that's consistent with this notion that it

3 oxidized and changed.

4 Q. What effect, if any, does Paragraph Number 4 have on your

5 opinions?

6 A. Well, I find Paragraph Number 4 to be a subjective

7 statement. Again, this reaction starts at the surface and

8 works its way down. And some of the cracks -- I mean, again,

9 it's happening at the surface, and to say that it's only a

10 minor portion of the entire suture, I think that needs to be

11 tested further.

12 Q. Do you know whether or not there were any images taken of

13 these -- of this polypropylene?

14 A. From my understanding, there were, yes.

15 THE COURT: Where did you get that idea?

16 THE WITNESS: From the report.

17 THE COURT: All right.

18 THE WITNESS: Sorry. I'll be more direct.

19 THE COURT: I was just trying to see if there was a

20 foundation to be laid here.

21 MR. WALLACE: Sure. 2026, any objection, Dave?

22 MR. THOMAS: Yeah, there is. I need to approach with

23 counsel on this.

24 THE COURT: Okay.

25 MR. WALLACE: We'll try to work it out ourselves.

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1 THE COURT: All right. 2026, when it's finished --

2 go ahead and bring her 2026 so we won't get behind here. All

3 of this has been about 2026.

4 MR. WALLACE: Thank you.

5 THE COURT: Got it worked out?

6 MR. WALLACE: I hope so. I believe so.

7 THE COURT: All right.

8 MR. THOMAS: That's my -- I'm sorry.

9 THE COURT: I'm sorry.

10 MR. THOMAS: That's my copy, I think you took.

11 (Laughter.)

12 MR. THOMAS: Got to have a program.

13 THE COURT: All right, Mr. Wallace.

14 BY MR. WALLACE:

15 Q. Dr. Guelcher, I made a mistake. When I spoke about the

16 SEM image, images that you might have seen, I linked them to

17 this human study. So I'm going to make my question really

18 simple and very clear for the record.

19 Have you seen any Ethicon documents where there are SEM

20 images of Prolene explants?

21 A. Yes.

22 Q. Okay.

23 MR. WALLACE: 14461 is the exhibit I'd like to offer,

24 Your Honor, and move it into evidence at the conclusion of the

25 case, absent counsel's position on it.

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1 MR. THOMAS: Your Honor, these are just kind of SEM

2 images in the air. They're not tied to anything. They're

3 scanning electronic microscopy images that aren't tied to

4 anything, and I don't think there's an adequate foundation for

5 them to be --

6 THE COURT: This time I have to sustain the

7 objection.

8 MR. WALLACE: That's fine. Thank you, Your Honor.

9 BY MR. WALLACE:

10 Q. You mentioned a dog study. Can you tell me whether or

11 not you reviewed any Ethicon documents relating to a dog study

12 and whether -- I will just leave it there.

13 A. Yes, I did.

14 Q. Okay. And did you review those documents in connection

15 with reaching your opinions in this case?

16 A. Yes, I did.

17 MR. WALLACE: 13152 would be the exhibit I'd like to

18 offer, Your Honor, absent an objection.

19 THE COURT: Is there an objection?

20 MR. THOMAS: No, Your Honor.

21 THE COURT: It may be received.

22 MR. WALLACE: Thank you, Your Honor.

23 (PLAINTIFFS' EXHIBIT P-13152 WAS RECEIVED IN EVIDENCE.)

24 THE COURT: Make sure there's a paper copy provided

25 to the Courtroom Deputy.

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1 MR. WALLACE: Can we pull up --

2 THE COURT: And provide it to the Courtroom Deputy.

3 BY MR. WALLACE:

4 Q. Can you please -- do you have it in front of you,

5 Dr. Guelcher?

6 A. Yes.

7 Q. Can you tell the jury what the document you have in front

8 of you is and the document that they have on the screen in

9 front of them?

10 A. So this is titled "Seven-Year Data for a Ten-Year Prolene

11 Study."

12 Q. And what is the date of that?

13 A. October 15th, 1992.

14 Q. And, in reviewing this document in connection with the

15 work that did you in this case, what conclusions did you draw?

16 A. Well, this document, again, showed evidence that the

17 polypropylene was changing and cracking on the surface of the

18 suture, that the Prolene suture was changing with time and

19 cracking.

20 Q. In the interest of time, Dr. Guelcher, I want you to look

21 at the conclusions that are found on the second page in the

22 middle of the document.

23 A. Yes.

24 Q. And I'm just going to take those, again, one at a time.

25 Can you -- and you have reviewed the entirety of this

Page 132

1 all the dogs at seven years so they could get the data.

2 That's my understanding.

3 Q. And let's move on to the second bullet point. Tell me

4 what, if anything, this second conclusion -- what impact, if

5 any, it had on your opinions.

6 A. So the second conclusion states that degradation in

7 Prolene is still increasing, and PVDF, which is another

8 material that is less susceptible, so it's less reactive with

9 oxygen, PVDF was more stable, in terms of cracking. So my --

10 what I learned from this was that, with the increased time,

11 the degradation of Prolene is continuing. This is consistent

12 with the idea that the foreign-body reaction doesn't stop. It

13 just keeps going until the material is removed.

14 Q. Can you move on to the third conclusion and tell the

15 jury, what, if any, impact that had on your opinions in this

16 case?

17 A. Well, this is, again, noting that this reaction starts at

18 the surface, so the eight explanted Ethilon sutures all showed

19 heavy cracking, in many cases abrasion of the dyed surface

20 layer. A decrease in the suture diameter was apparent in

21 several cases. So Ethilon is a different type of material.

22 It was also degrading. And they noticed a decrease in the

23 diameter of the suture which, again, is consistent with this

24 idea that it starts at the surface and works its way in, until

25 you're gradually losing material until it works its way to the

Page 131

1 document?

2 A. Yes. It's very long. Yes.

3 Q. Can you tell me what impact that first bullet point

4 that's the conclusion there had on your opinions in this case?

5 A. The seven-year in vivo results generally substantiated

6 the five-year findings. They closely correspond to the

7 observations of the explanted sutures of the dog that died

8 prematurely, and these findings were that the Prolene was

9 cracking with time and that was increasing with time.

10 Q. I'd like just -- just to take a step back and give the

11 jury a little bit of context for this study. What do you

12 understand the study, this study to be about and how long it

13 went?

14 A. So, from my reading of the document, this study was

15 designed to be a ten-year study in dogs, to understand the

16 stability of the Prolene suture. So what happens -- how does

17 the Prolene suture change over time, and it's implanted in a

18 dog because this is -- we can do this in animals. You can't

19 do these type of experiments in humans, and the dog is a good

20 model, it's a large animal model. And so we can use these

21 data to tell us something about how Prolene sutures would

22 respond and how stable they are, how they'll react in a human.

23 And, again, it was designed to be a ten-year study.

24 One of the dogs died prematurely, not related to the suture,

25 at six years and ten-and-a-half months, and so they sacrificed

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1 middle of the suture.

2 Q. Just a point of clarification, Dr. Guelcher. Are --

3 PVDF, that's not Prolene, is it?

4 A. No, that's a different material. That's polyvinylidene

5 fluoride. That's chemically different from polypropylene.

6 Q. Thank you.

7 Let's just move right on to the fourth bullet point.

8 And tell the jury what impact, if any, that had on your

9 opinions in this case.

10 A. Well, in this other type of material, they did not find

11 any cracks. There were some scratches. What this tells me,

12 that these four materials that they implanted were all

13 degrading at different rates. Some of them were more affected

14 by the reactive oxygen than others.

15 Q. Is Novafil polypropylene?

16 A. No.

17 Q. How -- how have the human Prolene suture study and this

18 dog study, how have they impacted your opinions on mesh, if at

19 all?

20 A. So, both the human explants that were explanted from

21 humans out to eight years and the seven-year dog study both

22 show that the polypropylene, the Prolene polypropylene, reacts

23 with the oxygen that's secreted by these inflammatory cells

24 and it changes the structure over time. So, as we progress

25 from one to five, seven, eight years, these changes get more

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1 severe, we see more cracking, more oxidation, more changes in
2 the properties of the polypropylene.

3 This is basically happening because of this
4 foreign-body reaction. And, in my opinion, these changes,
5 because the mesh is also made from propylene, this reaction
6 with oxygen, these changes in the surface will also occur with
7 the mesh because it's made from the same base material,
8 propylene.

9 Q. So, I'll try to ask it this way, Dr. Guelcher. Does the
10 fact that this is a Prolene suture affect at all your opinion
11 on what you referred to as the more-mesh opinion?

12 A. So, I think it's very important to remember that a suture
13 implanted under the skin or in a blood vessel is very
14 different than mesh implanted in the pelvic floor. Mesh has a
15 lot more polypropylene, a lot more Prolene, a lot more
16 surface, that can react with this oxygen.

17 So, I think what we can learn from the suture study is
18 that the Prolene is unstable and it reacts in the body.
19 Whether -- in this -- in my view, would lead to more studies
20 with the mesh actually in the anatomic location where I want
21 to use it, in the pelvic floor.

22 How does this oxidation affect the mesh in the pelvic
23 floor? This is, to me, an important unanswered question. But
24 what these studies point to is that Prolene does change over
25 time. That's my conclusion.

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1 Q. Well, since we're talking about Ethicon documents, beyond
2 the documents that the jury has seen and that have been
3 offered into evidence, did you review any other Ethicon
4 documents?

5 A. I reviewed a number of other Ethicon documents. These
6 are the two that struck me as the most -- in forming my
7 opinions.

8 Q. And in reviewing those Ethicon documents, did you see any
9 other studies like these that were actually done on the TVT-O
10 mesh or mesh of any kind?

11 A. There are a number of other studies looking at mesh,
12 complications of mesh, and what happens to mesh when it's
13 implanted in the body.

14 Q. Well, my question is more specific than that,
15 Dr. Guelcher.

16 My question is, specifically, in all of the internal
17 company documents that you reviewed, did you see whether or
18 not Ethicon ever did any sort of explant studies on their
19 mesh?

20 A. I haven't seen those documents, no.

21 Q. Is that at all important to you as a biomedical engineer
22 and how it might impact your opinions in this case?

23 MR. THOMAS: Objection, Your Honor.

24 THE COURT: Sustained.

25 BY MR. WALLACE:

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1 Q. Now, when you looked at these Ethicon documents, who
2 provided those to you?

3 MR. THOMAS: I'm going to object to the generic
4 description of documents. I really don't know what he's
5 talking about. I don't think the witness does either.

6 THE COURT: Sustained. The documents that have been
7 admitted into evidence, you may inquire about certainly.

8 MR. WALLACE: Thank you.

9 THE COURT: I'm not trying to limit you. I'm just
10 trying to hurry it.

11 MR. WALLACE: Okay. Sure. Then why don't I move on.

12 BY MR. WALLACE:

13 Q. Did you -- in connection with the work that you've done
14 on polypropylene, have you reviewed any literature?

15 A. Yes. There is a number of published papers on these
16 meshes and how they respond.

17 Q. In connection -- are you familiar with Drs. Costello and
18 Clavé?

19 A. Yes.

20 Q. Have you reviewed their work?

21 A. Yes, I have.

22 Q. Can you tell the jury -- can we go to the --

23 MR. THOMAS: Before you publish anything, may I have
24 a copy of whatever you're going to publish?

25 MR. WALLACE: It's in the PowerPoint.

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1 MR. THOMAS: Well, it's quotes from the study. I
2 object to this, isolated quotes from the study, Your Honor, as
3 opposed to the full study.

4 THE COURT: Do you have a copy of the full study that
5 you can provide counsel? If that's what you plan to
6 introduce.

7 MR. WALLACE: It's just the articles. They're marked
8 as exhibits. I'll give you the exhibit numbers, David. I
9 believe you have a copy in front of you.

10 THE COURT: Why don't you two get together.

11 MR. WALLACE: Sure.

12 THE COURT: Maybe over that way a little bit.

13 (Discussion held off the record between Mr. Wallace
14 and Mr. Thomas.)

15 MR. WALLACE: Your Honor, may I proceed?

16 THE COURT: You may.

17 MR. WALLACE: And, Mr. Thomas, you have the article.

18 BY MR. WALLACE:

19 Q. In connection with your work, did you perform a
20 literature search?

21 A. Yes, I did. I searched a number of papers on this.

22 Q. And in connection with your work, did you come across any
23 articles that dealt with polypropylene degradation in
24 explants?

25 A. Yes, I did.

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1 Q. And what articles were those?

2 A. Well, I've selected three that I believe make the point,

3 by Clavé, et al., and published in 2009; by Costello, et al.,

4 published in 2007; and by Wood, et al., published in 2013.

5 Q. And, for the record, the Clavé article is Exhibit 21457.

6 A. Yes, that's right.

7 MR. WALLACE: And absent an objection, I'd like to be

8 able to publish it to the jury.

9 THE COURT: 21 -- the number is?

10 MR. WALLACE: 21457.

11 THE COURT: 21457 may be admitted when presented to

12 the Courtroom Deputy.

13 (PLAINTIFFS' EXHIBIT P-21457 WAS RECEIVED IN EVIDENCE.)

14 MR. WALLACE: Thank you.

15 Your Honor, as a learned treatise, we'd -- it's my

16 understanding we would not be ultimately providing that to the

17 jury.

18 THE COURT: All right.

19 THE DEPUTY CLERK: It does not go to the jury?

20 THE COURT: That's correct.

21 MR. WALLACE: Correct. But we would like to publish.

22 MR. THOMAS: Yes.

23 MR. WALLACE: Thank you.

24 BY MR. WALLACE:

25 Q. So let's keep moving on, Dr. Guelcher. The article is in

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1 front of the jury, at least the first page is. Can you tell

2 us why you found that article significant?

3 A. So, this article was interesting because the authors

4 looked at a hundred explants, a hundred meshes removed from

5 human patients, and tried to understand what was happening in

6 terms of the response these materials had on the body.

7 Q. Could you turn to what would be the fourth page, second

8 column on the right, beginning with the word "analysis"? Do

9 you see that?

10 A. Yes.

11 Q. Okay. Do you recall what sort of analysis was done by

12 the authors that conducted this study?

13 A. Well, they did scanning electron microscopy, or SEM,

14 which is a way for looking at the surface of the material.

15 They did this infrared spectroscopy, which is a way of looking

16 at the chemical groups, chemical bonds on the surface.

17 Q. What does it mean when it says "uneven way"?

18 A. Well, "uneven way" would mean that it's -- it's maybe

19 random, it's associated with manufacturing, not other types of

20 responses.

21 Q. If you could turn to Page 267, please, and look at the

22 area -- the jury has it highlighted in front of them --

23 talking about the chronic inflammatory reaction. Can you tell

24 us --

25 A. Yes.

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1 Q. -- whether or not this is at all consistent with your

2 opinions in this case?

3 A. So, this first paragraph explains the chronic

4 inflammatory reaction, in a way that I was explaining as a

5 foreign-body reaction. So this is free radical synthesis as

6 peroxide, superoxide and hypochlorite. These are all reactive

7 oxygen. They're forms of oxygen that are much more reactive

8 than oxygen that's in the air you breathe. So this would be

9 what I was referring to as reactive oxygen species.

10 And then the next sentence says, "Once in contact with

11 the polypropylene implant, these radical species could infer

12 oxidation of the carbon-hydrogen bonds." This is what I was

13 explaining earlier. These radical species or reactive oxygen

14 species that are secreted by inflammatory cells, that oxidize

15 that carbon-hydrogen bond. That is what I was explaining

16 earlier.

17 Q. Do you know -- I'm sorry. Did I interrupt you?

18 A. No. I'm done.

19 Q. Do you know where these 100 explants came from, what part

20 of the body?

21 A. I believe these were pelvic mesh explants, vaginal mesh.

22 Q. Is there anything else that -- in connection with this

23 study, that -- well, let's just move on to the next article.

24 Why don't we do that.

25 The Costello article which is 21468, do we have that?

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1 THE COURT: Another learned treatise?

2 MR. WALLACE: Yes, Your Honor.

3 THE COURT: All right.

4 (PLAINTIFFS' EXHIBIT P-21468 WAS RECEIVED IN EVIDENCE.)

5 BY MR. WALLACE:

6 Q. Why did you select this article, Dr. Guelcher?

7 A. Well, this was another article, this is from hernia mesh,

8 but it also explains very clearly how the body can react to

9 implanted polypropylene mesh.

10 Q. What else, if anything, did you find significant about

11 this article?

12 A. Well, this article found evidence of surface cracking,

13 just like we saw in the Ethicon studies. There was surface

14 cracking, there was also surface degradation of the material,

15 by spectroscopy, and there was also a change in the

16 molecular weight of the polypropylene that was explanted from

17 these --

18 THE COURT REPORTER: I'm sorry. The what.

19 THE WITNESS: The molecular weight -- not the

20 molecular weight. I'm sorry. I spoke incorrectly.

21 The melting temperatures changing in these, as well.

22 And so these meshes are showing changes in response

23 to this foreign-body reaction, just like we've seen

24 previously.

25 BY MR. WALLACE:

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1 Q. If you look at the second page of the article reporting
 2 on this study, beginning with the paragraph that says, "As a
 3 result of this chronic inflammatory response" --
 4 A. Yes.
 5 Q. -- "the mesh material is exposed to a continuous bath of
 6 oxidants."
 7 A. Yes.
 8 Q. Do you see that paragraph?
 9 A. Yes.
 10 Q. Can you tell the jury the significance of this paragraph
 11 to your opinions in this case?
 12 A. So this paragraph supports my opinions that this chronic
 13 inflammatory response, this is a foreign-body reaction. The
 14 mesh material is exposed to a continuous bath of oxidants.
 15 Again, these oxidants are reactive oxygen species, more
 16 reactive than molecular oxygen, and the mesh is continuously
 17 exposed to these materials because the cells are adherent and
 18 they secrete these reactive oxygen, and this reaction
 19 continues as long as the mesh is there. So these statements
 20 are supporting the opinions I --
 21 Q. This study talks about both chemical degradation and
 22 physical degradation. What is -- what does that mean in
 23 connection -- as it relates to your opinions?
 24 A. Well, chemical degradation would be these changes in the
 25 chemical structure of the polypropylene and this degrading,

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1 articles confirm your opinion on degradation?
 2 A. Yes, they do. Again, this study saw evidence of changes
 3 in the polypropylene, cracking, changes in the physical
 4 properties of the polypropylene over time.
 5 Q. Are these the only three studies that exist in the
 6 literature on these issues, Dr. Guelcher?
 7 A. No. There are other studies that have shown this as
 8 well, that polypropylene responds to this foreign-body
 9 reaction and changes, its chemical properties change and its
 10 mechanical structural properties change.
 11 Q. You talked about the less-mesh concept in the summary of
 12 your opinions. I'd like us to move to Slide 17, please.
 13 MR. WALLACE: If that's -- before we go there, let's
 14 make sure there is no objection.
 15 MR. THOMAS: I just have one of the studies
 16 referenced on the slide. Are you going to introduce both
 17 studies on the slide?
 18 MR. WALLACE: We're just going to talk about them. I
 19 won't introduce them.
 20 MR. THOMAS: I object to the reference to the slide
 21 if they're not going to be part of the record in the case.
 22 THE COURT: Just ask the question.
 23 MR. WALLACE: Fair enough.
 24 BY MR. WALLACE:
 25 Q. Have you reviewed the Cobb study regarding lightweight

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1 and, again, these chemical changes can lead to physical
 2 changes such as embrittlement and cracking, which is what was
 3 observed in this study is these chemical changes lead to
 4 physical changes such as cracking in the material.
 5 Q. Let's keep moving, Dr. Guelcher. And you mentioned the
 6 Wood article.
 7 MR. WALLACE: Counsel, that would be 21925. Again,
 8 another learned treatise, Your Honor.
 9 THE COURT: All right.
 10 (PLAINTIFFS' EXHIBIT P-21925 WAS RECEIVED IN EVIDENCE.)
 11 BY MR. WALLACE:
 12 Q. And, Dr. Guelcher, have you reviewed this study in
 13 connection with your work?
 14 A. Yes, I have.
 15 Q. And do you know when it was published?
 16 A. This study was published just last year, 2013.
 17 Q. And what is the significance of this study to you in
 18 connection with your opinions in this case?
 19 A. So, what I found interesting about this study is these
 20 were three different types of materials that were removed from
 21 the same patient, so it gives us a reference for how three
 22 different types of materials respond to the foreign-body
 23 reaction in the same patient. So it takes out of
 24 consideration the patient-to-patient changes.
 25 Q. Do these studies that you've looked at in these three

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1 mesh in hernia repair?
 2 A. Yes, I have.
 3 Q. And have you reviewed that in connection with the
 4 opinions that you'd offered on the less-mesh concept?
 5 A. Yes.
 6 Q. Okay. And what, if anything, does the Cobb paper -- or
 7 how does the Cobb paper inform your opinions in this case?
 8 A. So, the argument in the Cobb paper is that less mesh is
 9 better. And this relates back to my opinions in that if the
 10 polypropylene is causing the surface reaction and the
 11 polypropylene is responding to that foreign-body reaction and
 12 changing, the more polypropylene surface that's present, the
 13 greater those changes would be, the more hazardous they could
 14 be, and so because of this reaction, the polypropylene in
 15 response to the body, it's best to minimize the amount of
 16 polypropylene that's present in the mesh. This is the
 17 argument that Cobb, et al., are making and is consistent with
 18 my opinions.
 19 Q. Have you reviewed the work of Dr. Klinge and
 20 Klosterhalfen in the foreign-body reaction to mesh's paper?
 21 A. Yes, I have.
 22 Q. And did that --
 23 MR. THOMAS: Your Honor --
 24 THE COURT: Yes.
 25 MR. THOMAS: That's not sufficiently identified.

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1 There are dozens, as the Court's well aware, of papers between
2 Klinge and Klosterhalfen on different issues.

3 THE COURT: All right. If you would identify which
4 studies or papers you're talking about.

5 It's time for our afternoon break, I think, if you're
6 going to be going for a little bit longer.

7 MR. WALLACE: Actually, no, Your Honor.

8 THE COURT: Oh, really?

9 MR. WALLACE: I will be done -- if we take a break, I
10 can probably get organized and get done relatively quickly.

11 THE COURT: All right. Ladies and gentlemen, we'll
12 take our afternoon break. I'll call you back in 15 minutes.

13 Don't discuss the case among yourselves. Prevent
14 anyone from discussing it with you or in your presence. I
15 will call you back shortly. Don't use any social media.

16 COURT SERVICES OFFICER: All rise.

17 (The jury left the courtroom at 2:30 p.m.)

18 (The jury entered the courtroom at 2:47 p.m.)

19 THE COURT: You may resume the stand.

20 Mr. Wallace.

21 MR. WALLACE: Thank you. Dr. Guelcher, we're going
22 to proceed.

23 BY MR. WALLACE:

24 Q. I want to go back really briefly just to try to finish up
25 to 21925, and that is the Wood article, and the section on

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1 A. I did. I mentioned that these types of chemical changes

2 can result in mechanical failure of the devices as was

3 observed with the pacemaker lead problem.

4 Q. You gave the jury a few dates about, for example, when

5 foreign body reaction was known and when degradation outside

6 the body was known. Do you know, in connection with reviewing

7 these articles and the work that you've done in the case, when

8 the first study was done to evaluate vaginal mesh implants and

9 the concepts of degradation?

10 A. Well, the Clavé paper that we were discussing earlier,

11 this Clavé paper was published in 2005, so in 2005 they noted
12 that --

13 Q. Let's make sure we're looking at the right document. I'm
14 looking at 21457 which was actually a 2010 publication.

15 A. Yes. Oh, I got the date mixed up. I'm sorry.

16 21457 is this Clavé study, I was looking at the date
17 wrong.

18 Q. And are you looking at the conclusion section?

19 A. I'm looking at the conclusions where they state this is
20 the first study to evaluate synthetic implants used in the
21 vaginal approach.

22 Q. And have you seen any evidence in the work that you've

23 done in this case or any of the work that you've done with

24 respect to polypropylene that Ethicon has done such research?

25 A. I've not seen any research from Ethicon in this area, and

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1 polypropylene on page 1120.

2 A. Yes.

3 Q. And I'm going to ask you to look at the words beginning
4 with "unfortunately". And I'll read it for you, Dr. Guelcher.

5 "Unfortunately, polypropylene will degrade in an oxidizing
6 environment such as the environment during a foreign body
7 response. Because of this, polypropylene has been shown to
8 oxidize in vivo. Oxidization of polypropylene results in
9 surface cracking and cracking, changes in mechanical strength
10 and increased brittleness."

11 Did I read that correctly.

12 A. Yes.

13 Q. And what impact, if any, did this Wood article and what I
14 just read have on your opinions in this case?

15 A. So this Wood article, again, is consistent with my
16 opinion that this oxidizing environment, this is the space
17 between the cell, the cell and the material where we have all
18 this reactive oxygen, that's an oxidizing environment. It
19 says, "such as the environment during the foreign body
20 response." That's the environment I was speaking about. And
21 polypropylene oxidizes in vivo which can cause these changes
22 in chemical composition and also mechanical properties such as
23 brittleness and cracking.

24 Q. Did you address mechanical failure in your report in this
25 case?

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1 again after seeing the degradation of the sutures, as an

2 engineer I would want to know how the Prolene responds to this

3 oxidated environment in the pelvic floor and the mesh, quite

4 different than a suture, but to my knowledge that study has

5 not been done.

6 Q. In connection with your work, did you have to determine
7 whether or not polypropylene was inert?

8 A. Yes, I did.

9 Q. And what did you find?

10 A. Well, based on the testimony that I provided earlier, I
11 do not believe polypropylene is inert. It is oxidatively
12 unstable, it reacts with oxygen, and its chemical composition
13 changes, so I would not call this an inert material because of
14 its reactivity with oxygen.

15 Q. Are there any limitations on the use of polypropylene in
16 the pelvis for a permanent implant as it relates to your
17 opinions in this case?

18 MR. THOMAS: Objection, Your Honor.

19 THE COURT: Let me see you at sidebar.

20 (The following occurred at sidebar.)

21 THE COURT: Mr. Thomas.

22 MR. THOMAS: Yes, Your Honor. That's an opinion that
23 goes directly to the use of mesh in the pelvic floor which is
24 beyond the scope of his expert report.

25 MR. WALLACE: Your Honor, I would just say that I

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1 could probably word the question differently and I would go
2 back and just say with respect to his qualifications as a
3 biomedical engineer who's offered his opinions on the case,
4 whether or not as a biomedical engineer there are any
5 limitations with respect to the use of polypropylene inside
6 the pelvis as a biomedical engineer, not a clinical.

7 THE COURT: I'm not sure you still would have
8 established an adequate foundation even if you asked that, but
9 if you want to try to establish a foundation, I'll let you,
10 but that alone I would sustain the objection.

11 MR. WALLACE: Okay. If I could ask, and when you
12 speak of foundation, Your Honor --

13 THE COURT: Well, that is to say as a biomedical
14 engineer, are you familiar with and have you studied chemical
15 composition of the tissues and so forth, and do you have
16 medical training?

17 MR. WALLACE: Okay. And I'll clarify just so with
18 respect to other witnesses, Your Honor, I will be clarifying
19 that he's not a medical doctor, not offering a clinical
20 opinion.

21 THE COURT: Yes. Great. Thank you.

22 MR. WALLACE: Thank you.

23 (Sidebar concluded.)

24 MR. WALLACE: Dr. Guelcher, I have just a few more
25 questions.

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1 MR. WALLACE: Do you want me to respond, Your Honor?

2 THE COURT: Sure.

3 MR. WALLACE: I understand that he's not a medical
4 doctor. My question is going to be very simple, whether or
5 not he believes that the statement that polypropylene is not
6 subject to degradation is true or false. He's not offering a
7 clinical opinion. I believe he can say as a matter of fact
8 just what he reviewed and we would still be able to, allowed
9 to offer admission of the IFU and those issues. Would that be
10 acceptable, Your Honor?

11 MR. THOMAS: He's already given his opinion about
12 polypropylene degradation and I think this is inappropriate
13 for this witness.

14 THE COURT: I'll overrule the objection.

15 MR. WALLACE: Your Honor, may I publish the document?

16 THE COURT: You may.

17 (Sidebar concluded.)

18 MR. WALLACE: Your Honor, rather than -- I'm sorry, I
19 might have interrupted.

20 THE COURT: I was going to see if you were going to
21 introduce that.

22 MR. WALLACE: What I would like to do, so that the
23 next witness can talk about it from a clinical perspective,
24 Your Honor, is that I would use one of my opening slides as
25 just a demonstrative with this witness.

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1 BY MR. WALLACE:

2 Q. With respect to polypropylene's use inside the body, a
3 very simple question, are you anti-polypropylene when it comes
4 to using polypropylene in other parts of the body?

5 A. No, I'm not opposed to the idea of using polypropylene in
6 the body. One of the important definitions about --

7 MR. THOMAS: Objection, Your Honor. I object to the
8 narrative. He answered the question.

9 THE COURT: I'll sustain it. He gave a direct answer
10 to the question, so I'll sustain it.

11 MR. WALLACE: Yes, Your Honor.

12 If you'll indulge me for one minute, Your Honor.

13 THE COURT: Certainly.

14 MR. WALLACE: I have one more thing.

15 (Discussion was held off the record.)

16 MR. THOMAS: Your Honor, I expect we're going to need
17 to talk about this.

18 THE COURT: All right. Excuse us.

19 (The following occurred at sidebar.)

20 THE COURT: Mr. Thomas.

21 MR. THOMAS: Mr. Wallace advises the next exhibit he
22 wants to use with this witness is an instructions for use and
23 I can't imagine what this witness brings. There's nothing
24 about instructions for use in the opinions that he's disclosed
25 in this case.

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1 THE COURT: Why don't I just allow you to ask the
2 question again?

3 MR. WALLACE: Okay.

4 BY MR. WALLACE:

5 Q. Let me ask it this way: If the instructions for use that
6 come with this product, the TVT-O product, say that the
7 product does not degrade, is that a true or false statement?

8 MR. THOMAS: Objection, Your Honor, to the
9 characterization.

10 THE COURT: Overruled.

11 THE WITNESS: So what I've spoken about today is the
12 response of the body -- the response of polypropylene to the
13 foreign body reaction.

14 MR. THOMAS: Objection, Your Honor.

15 THE COURT: Sustained. Non-responsive.

16 BY MR. WALLACE:

17 Q. Can you just answer whether it's true or false?

18 A. I'm trying to give an explanation.

19 THE COURT: You can answer it and then give an
20 explanation.

21 THE WITNESS: Well, last time I tried that I wasn't
22 allowed.

23 THE COURT: Well, consistency is the hobgoblin of
24 small minds.

25 THE WITNESS: That's a good one for a professor, I

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1 think.

2 I don't believe that's true. I believe that I

3 pointed to evidence today that shows that polypropylene reacts

4 in response to a reactive oxygen secreted by the foreign body,

5 by inflammatory cells, by inflammatory cells the polypropylene

6 degrades, its chemical composition changes, it becomes

7 brittle, cracks, and undergoes other changes, and this could

8 have negative effects on a patient's health when implanted in

9 the pelvic floor. So I don't believe --

10 THE COURT: The jury will disregard last part of the

11 witness's answer.

12 MR. WALLACE: Thank you, Your Honor.

13 Let's go to the summary of opinions slide so we can

14 finish, Dr. Guelcher.

15 THE COURT: I meant the part about his idea that it

16 could have effect on the patient's health. You're to

17 disregard that and not consider it.

18 I can't answer your questions.

19 THE DEPUTY CLERK: They want to be able to see the

20 slide.

21 THE COURT: Oh, the slide coming up. Sure. You're

22 ahead of me. All right.

23 MR. WALLACE: Thank you, Judge.

24 BY MR. WALLACE:

25 Q. With respect to the opinions that you've offered in your

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1 report and your testimony today and this summary of opinions,

2 have you held each of these opinions to a reasonable degree of

3 biomedical engineering and chemical engineering certainty?

4 A. Yes, I have.

5 MR. WALLACE: I have no further questions.

6 THE COURT: Thank you, Mr. Wallace.

7 Cross examination.

8 MR. THOMAS: Thank you, Your Honor.

9 CROSS EXAMINATION OF SCOTT GUELCHER, Ph.D., BY MR. THOMAS:

10 Q. Dr. Guelcher, how are you today?

11 A. Good. How are you?

12 Q. Doctor, you testified on direct that polypropylene is a

13 polymer?

14 A. Yes.

15 Q. It was invented in 1950s, correct?

16 A. Yes.

17 Q. And when polypropylene was invented, it was very

18 innovative, wasn't it?

19 A. I mean all materials when they're invented, they're

20 innovative.

21 Q. Plastics, right? The age of plastics and that was a

22 plastic, correct?

23 A. Yes, it is a plastic.

24 Q. Now, Prolene is the brand name for the polypropylene

25 Ethicon uses in its medical devices, correct?

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1 A. Prolene is a brand name, it's essentially polypropylene

2 with antioxidants and lubricants.

3 Q. And Ethicon first used Prolene in its sutures?

4 A. That's my understanding.

5 Q. And sutures are what we in West Virginia call stitches,

6 right?

7 A. Call them that in Virginia, too, where I grew up.

8 Q. Down in Blacksburg?

9 A. Yes, sir.

10 Q. And so Ethicon Prolene stitches or sutures have been

11 around since the late Sixties?

12 A. That's my understanding, they've been around since the

13 Sixties.

14 Q. And what makes Prolene Prolene as opposed to simple

15 polypropylene are the additives that you talked about,

16 correct?

17 A. Yes. The brand name Prolene is defined by the additives

18 that are added to the polypropylene.

19 Q. And those additives are calcium stearate, do you remember

20 that?

21 A. Calcium stearate is added as a lubricant.

22 Q. And DLTDP because I can't pronounce the full word.

23 A. It's a long word. It's an antioxidant.

24 Q. Santonox R?

25 A. Another antioxidant.

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1 Q. Procol LA-10?

2 A. I think that's another surfactant.

3 Q. And a CPC --

4 THE COURT: That's another what? I didn't hear it.

5 THE WITNESS: I'm sorry. It's another surfactant or

6 a lubricant.

7 THE COURT: All right.

8 BY MR. THOMAS:

9 Q. And then the coloring, the CPC pigment, correct?

10 A. Yes, sir.

11 Q. And those additives are what make Prolene different from

12 the other polypropylene medical devices on the market,

13 correct?

14 A. There are many different grades of polypropylene; Marlex,

15 Prolene, different grades --

16 THE COURT: Is that a yes or a no?

17 THE WITNESS: I'm sorry. Yes.

18 MR. THOMAS: Thank you.

19 BY MR. THOMAS:

20 Q. Now, Ethicon Prolene sutures are what is known as

21 non-absorbable sutures, correct?

22 A. They're marketed as non-absorbable.

23 Q. Okay. And what that means is they are supposed to be in

24 the body for life?

25 A. They're supposed to be without changing, yes.

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1 Q. Do you know where Ethicon gets the polypropylene resin
2 used to make Prolene sutures?
3 A. My understanding it comes from Sunoco and is compounded
4 in a plant in Kenova on the Kanawha River.
5 Q. It's made here in West Virginia?
6 A. Yes, it is.
7 Q. And it has been since the beginning of the time they made
8 these sutures, correct?
9 A. My understanding is the plant has changed control, but
10 it's still made in the same plant, it's been bought and sold
11 though.
12 Q. And you know when Ethicon buys this resin from this plant
13 in Kenova, it actually comes down to Kenova and takes over the
14 plant and makes special runs of the Prolene polypropylene at
15 this plant, correct?
16 A. I wouldn't agree that they take over the plant. My
17 understanding is that they work with the personnel in the
18 plant to make sure that Ethicon's concerns are addressed
19 during the campaign.
20 Q. Do you agree that Ethicon personnel thoroughly clean the
21 mixing and compounding equipment before running our Prolene
22 material, Ethicon's Prolene material?
23 A. You're reading that from a document.
24 THE COURT: Would you agree with that or not, or do
25 you know?

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1 THE WITNESS: I don't know the level of detail that
2 -- I know that they're there and that they're working. This
3 is a common practice, you work with a sole manufacturer to
4 make sure things are done. I'm speaking on my experience.
5 THE COURT: Well, Doctor, the important thing here is
6 just listen to the question and try to answer it as asked. He
7 has asked you a question, whether you know -- would you finish
8 it again there, Mr. Thomas?
9 MR. THOMAS: Your Honor, with the court's permission,
10 I'm going to try to make it a little easier. May I approach
11 the witness?
12 THE COURT: You may.
13 BY MR. THOMAS:
14 Q. Doctor, I'm going to hand you what's been marked as
15 defendant's exhibit 23600. It's a document dated January 23,
16 2003.
17 A. Yes.
18 Q. And it's titled Prolene resin manufacturing
19 specifications.
20 A. Yes.
21 Q. You've seen this document before, haven't you?
22 A. I have seen this document.
23 Q. And this 2003 document discusses the Prolene
24 manufacturing process in Kenova, West Virginia, doesn't it?
25 A. Yes, sir, it does.

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1 MR. THOMAS: And Jamie, would you give me the first
2 page of that, please, so the jury can see it?
3 THE COURT: Do you want to move its admission?
4 MR. THOMAS: I do, Your Honor. Thank you.
5 THE COURT: Is there objection?
6 MR. WALLACE: No, Your Honor.
7 THE COURT: It may be received and displayed.
8 (DEFENDANTS' EXHIBIT 23600 WAS RECEIVED IN EVIDENCE.)
9 MR. THOMAS: Let's go to the first paragraph, Jamie.
10 BY MR. THOMAS:
11 Q. Do you recall from reading this document, Mr. Guelcher,
12 that back in the Sixties Ethicon went to a company in New York
13 to try to figure out what kind of polypropylene they were
14 going to use in their Prolene sutures, correct?
15 A. That's what it says here.
16 Q. Okay. And they obtained numerous different fiber samples
17 and tested those samples before they chose the one they wanted
18 to use, correct?
19 A. Yes. It doesn't say how, but it says that.
20 Q. Okay. And down in the second paragraph it says that
21 Ethicon personnel could go into the plant to insure that the
22 resin was made under proper conditions of cleanliness,
23 etcetera, and to verify that the formulations were as stated
24 on the run sheets. You knew that, didn't you?
25 A. I'm sorry. What page are you on?

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1 Q. On the front page in the second paragraph, right in the
2 middle.
3 A. Okay. Mine is organized a little differently. I see.
4 Various deals were struck, Ethicon could go into the plant.
5 That's what I was saying earlier, yes.
6 Q. Okay. And they bought multi-year supplies at one time,
7 do you remember that from reading the document?
8 A. What I understand is they would do a campaign every
9 couple years, they would make a lot of material.
10 Q. So the current practice, end of that paragraph, of week
11 to two week long campaigns every two years, that's how they
12 made their Prolene, correct?
13 A. That's what it says.
14 Q. And so you go down to the bottom of the third paragraph.
15 From the beginning of the Sixties, Ethicon has always bought
16 its Prolene from the same plant using the same equipment, with
17 the exception of the polymer reactor, and made by the same
18 people, except for those who have been retired or replaced,
19 correct?
20 A. That's what it says, yeah.
21 Q. Now, the second page of that document lists the additives
22 that are in Prolene that we talked about a minute ago,
23 correct?
24 A. Yes, sir.
25 Q. And the next paragraph tells about the manufacturing

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1 process for Prolene. And Ethicon insists that the mixing and
 2 compounding equipment be thoroughly cleaned prior to running
 3 our material. Do you see that? Right under the additives.
 4 A. Under the additives. Yes. I see it.
 5 Q. And Aristech, the owner, and Ethicon inspect the
 6 equipment before commencing operations; do you see that?
 7 A. That's what it says.
 8 Q. And once they start the compounding campaign, the first
 9 500 to a thousand pounds that are compounded are discarded as
 10 a matter of course; do you see that?
 11 A. That's a fairly common practice, yeah, I understand.
 12 Q. And if the molecular weight of the natural, paren,
 13 unpigmented material is acceptable as measured by melt float,
 14 we then start collecting material. You know the importance of
 15 molecular weight here, don't you?
 16 A. I do, but I don't know what's acceptable means, the
 17 specification.
 18 Q. What's the importance of an appropriate molecular weight
 19 for polypropylene?
 20 A. Well, the molecular weight has an effect on the
 21 properties, but again, it should be within some specification.
 22 I don't know what's acceptable --
 23 Q. I didn't ask you that question. I'm asking you about
 24 molecular weight. And so it's important to have an
 25 appropriate molecular weight for the product before it's

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1 released, you'd agree with that?
 2 A. Molecular weight is typically something we put a
 3 specification on.
 4 Q. Okay. And you know this process hasn't changed over the
 5 last 50 years?
 6 A. That's what this document says.
 7 Q. Do you have any reason to disagree with that?
 8 A. There were some changes to the formulation, I understand,
 9 the antioxidants were changed in the early 1990s. That was
 10 changed. The plant actually changed owners I think a number
 11 of times.
 12 Q. But the equipment's the same?
 13 A. The facility and the equipment seem to be the same.
 14 Q. Do you have any idea of the uses of polypropylene Prolene
 15 sutures in the human body?
 16 A. I know that they're used as sutures for a number of
 17 applications.
 18 Q. Do you know whether they come in different sizes?
 19 A. I know that they come in different sizes.
 20 Q. Why do they come in different sizes?
 21 A. Well, I'm not a clinician, but I would assume you'd want
 22 different sizes for different types of surgeries that are
 23 being done.
 24 Q. Do you know how many Prolene sutures have been implanted
 25 in people around the world since the Sixties?

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1 A. That's not a statistic that I'm aware of.
 2 Q. Billions, with a B?
 3 A. Okay.
 4 Q. Do you have any idea whether to disagree with that or
 5 not?
 6 A. I said I don't know what the number is. It sounds like
 7 it's --
 8 Q. A bunch?
 9 A. It's a lot of hamburgers, yeah.
 10 Q. That's a legal term. I'm sorry. I apologize.
 11 You know from your review of your documents in this
 12 case that Ethicon began using Prolene polypropylene in hernia
 13 mesh in the mid 1970s, correct?
 14 A. Yes, that's my understanding.
 15 Q. And the, I think you testified that the mesh used in
 16 hernia mesh is a bigger piece of mesh, but exactly the same
 17 design as that used in TVT, correct?
 18 A. I don't think I said that. I don't think I was comparing
 19 hernia to --
 20 Q. Let me ask it this way: Do you know how the Ethicon
 21 Prolene hernia mesh compares to the Ethicon Prolene mesh used
 22 in TVT?
 23 A. My understanding is that similar mesh is just used in
 24 similar products but cut to different shapes, that's my
 25 general understanding.

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1 Q. Do you know whether the hernia mesh comes in bigger
 2 sheets than the mesh that's in the TVT?
 3 A. I would presume that it would since it's used for a
 4 different use than a sling.
 5 Q. And the Prolene used in the hernia mesh is the same
 6 chemical composition as the Prolene used in the sutures,
 7 correct?
 8 A. It's the same composition, but that doesn't mean it's
 9 going to respond the same.
 10 Q. I understand. I just asked you the composition.
 11 A. The composition is the same.
 12 Q. Okay. Do you know how many millions of Prolene
 13 polypropylene hernia meshes have been implanted in people
 14 around the world since 1975?
 15 A. I assume it's millions and not billions from what you --
 16 THE COURT: I couldn't hear you.
 17 THE WITNESS: I said it sounds like it's millions and
 18 not billions. I don't know the number.
 19 BY MR. THOMAS:
 20 Q. Okay. Now, you're aware from your work in this case that
 21 Ethicon polypropylene mesh began being used for the treatment
 22 of stress urinary incontinence in a TVT mesh in 1996; you know
 23 that, don't you?
 24 A. That's correct. To my knowledge.
 25 Q. And the Prolene mesh used for the treatment of stress

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1 urinary incontinence in the TVT mesh is the same chemical
 2 composition as the Prolene polypropylene mesh in the hernia
 3 mesh, correct?
 4 A. It's all sold as Prolene mesh, so I would assume it has
 5 the same composition.
 6 Q. Do you know?
 7 A. It's called Prolene, it's Prolene --
 8 THE COURT: Do you know?
 9 THE WITNESS: Yes. It's the same.
 10 BY MR. THOMAS:
 11 Q. So the Ethicon TVT mesh used for the treatment of stress
 12 urinary incontinence is also the same chemical composition as
 13 the Prolene suture, correct?
 14 A. It's the same chemical composition.
 15 Q. Do you know how many people have received, around the
 16 world, the Prolene mesh for the treatment of stress urinary
 17 incontinence?
 18 A. I don't know the exact number. I think it's in the
 19 thousands.
 20 Q. Okay. Now, prior to getting involved in litigation of
 21 these cases, you had not seen in any of your research that
 22 there was a problem with polypropylene mesh, true?
 23 A. I'm not studying in my research, research standard on
 24 polypropylene mesh --
 25 Q. Is that true?

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1 A. I think it's true. I'm not aware of any.
 2 Q. Now, prior to your work on these cases, you had never
 3 done research on polypropylene as an implantable biomaterial,
 4 true?
 5 A. Not researched polypropylene as an implantable
 6 biomaterial, but I've --
 7 THE COURT: True or not true?
 8 THE WITNESS: I've not done research on it as an
 9 implantable biomaterial.
 10 THE COURT: True or not true?
 11 THE WITNESS: True.
 12 BY MR. THOMAS:
 13 Q. Prior to getting involved in litigation of these cases,
 14 you had never published an article on the use of polypropylene
 15 in mesh, true?
 16 A. That's true.
 17 Q. And prior to getting involved in this litigation, you had
 18 never published any article on polypropylene specifically,
 19 true?
 20 A. That's true.
 21 Q. And prior to getting involved in this litigation, you had
 22 never given a presentation to any of your colleagues on
 23 polypropylene, true?
 24 A. That's true, but I am this fall.
 25 Q. Thank you. And indeed, prior to getting involved in this

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1 litigation, you had not even studied polypropylene, true?
 2 A. No, that's not true. And I know you're going to pull out
 3 my deposition on this, but --
 4 MR. THOMAS: Excuse me, Your Honor.
 5 THE COURT: Just wait. Just wait. Not a question
 6 pending right now.
 7 THE WITNESS: Yes, sir.
 8 MR. THOMAS: May I approach the witness, Your Honor?
 9 THE COURT: You may.
 10 BY MR. THOMAS:
 11 Q. Now, Dr. Guelcher, you've given depositions in this
 12 litigation before, correct?
 13 A. Yes, I have.
 14 Q. And the way depositions work, for the jury, maybe they
 15 don't know what a deposition is, you meet with a lawyer in the
 16 room and you swear to tell the truth and you answer questions
 17 about the litigation before you come in here to testify,
 18 correct?
 19 A. That's right.
 20 Q. And when you're asked questions you give truthful
 21 answers?
 22 A. I give truthful answers, but sometimes the context of the
 23 question can change from the deposition to a trial.
 24 Q. If you'll look at your March 25, 2014 deposition on page
 25 79, line three, and the question is asked -- do you have that?

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1 A. I do.
 2 Q. Okay. And the question is asked at line three, "And
 3 you've not studied polypropylene before your work in this
 4 case, correct?"
 5 "No. But I've studied oxidating degradation of other
 6 polymers?"
 7 Did I read that correctly?
 8 A. You read it correctly, but I think the word studied is
 9 vague.
 10 Q. Thank you.
 11 A. He's trying to impeach my testimony. Can I give an
 12 explanation? I have one.
 13 THE COURT: Stop. Now. I'm not going to put up with
 14 quarrelling from either side. The answer is "no". You've
 15 asked me if you may explain your "no" answer. The answer to
 16 that is "yes".
 17 THE WITNESS: Thank you, sir. I appreciate it.
 18 THE COURT: Go ahead.
 19 THE WITNESS: I'm sorry for the court.
 20 THE COURT: That's all right. I'm just doing what I
 21 do.
 22 THE WITNESS: I understand.
 23 I think the word studied in different contexts can
 24 mean different things. I had not done research on
 25 polypropylene prior to this litigation. I'm not hiding

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1 anything. But I have taught a course, developed a course on
 2 polymer science and engineering at Vanderbilt, I taught it for
 3 two semesters, other professors teach it now, and we talked
 4 about many types of polymers in this course. So I am familiar
 5 with polypropylene, but I do agree that I've not studied it in
 6 my research. So it's just this word that I am struggling a
 7 little bit with. If you asked me if I've done research, I
 8 would say no, I have not, but I have studied and I am aware of
 9 the material.

10 THE COURT: All right. Next question.

11 MR. THOMAS: Thank you, Your Honor.

12 BY MR. THOMAS:

13 Q. Now, you obviously know that Ethicon's TVT mesh is
 14 designed to be implanted in the human body?

15 A. Yes, that's correct.

16 Q. And you know when those meshes are removed from the human
 17 body then they're called an explant?

18 A. That's what I was explaining earlier.

19 Q. You have never analyzed a TVT mesh explant manufactured
 20 by Ethicon for the treatment of stress urinary incontinence,
 21 true?

22 A. I've not had any explant to --

23 Q. True?

24 A. -- characterize, so --

25 Q. I'm sorry. I don't mean to stop you, but --

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1 THE COURT: I apologize to Mr. Wallace and Mr.

2 Thomas, to you, Doctor. Proceed.

3 BY MR. THOMAS:

4 Q. In fact, Dr. Guelcher, you've never requested to analyze
 5 a mesh manufactured by Ethicon for the treatment of stress
 6 urinary incontinence, true?

7 A. Not directly. The company I work for has, I believe.

8 Q. Do you have your deposition in front of you again?

9 A. Yes.

10 Q. Turn to page 21, please, of your March 25 deposition.
 11 Are you there?

12 A. Yes.

13 Q. "Question: Have you ever requested to analyze a mesh
 14 manufactured by Ethicon for the treatment of stress urinary
 15 incontinence?"

16 "Answer: Not to my knowledge."

17 A. Yes.

18 Q. Thank you.

19 A. That's what I said.

20 Q. I need a little help from --

21 MR. WALLACE: Your Honor -- go ahead.

22 Your Honor, there was no impeachment there. I'd just
 23 move to just strike the entire questioning from the
 24 deposition. It wasn't the question that was asked.

25 THE COURT: Well, everybody's doing, ladies and

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1 THE COURT: I'll take that as an objection as
 2 non-responsive. I'll sustain the objection and direct the
 3 witness to answer the question as asked.

4 THE WITNESS: That's true, I've not tested it.

5 THE COURT: Can I see counsel at sidebar?

6 (The following occurred at sidebar.)

7 THE COURT: We're coming close or at least it seems
 8 to me to discussing the other mesh cases. I want just to be
 9 very sure we don't do that.

10 MR. THOMAS: I'm trying to tailor my questions to
 11 Ethicon specifically, Your Honor.

12 MR. WALLACE: Just fair warning, he has looked at
 13 mesh and you're about to open a can of worms.

14 THE COURT: He was specific that it was only Ethicon
 15 and I'm worried about the witness --

16 MR. WALLACE: I'm not sure he completely gets where
 17 he's going.

18 THE COURT: Are you going to ask more questions about
 19 that, explant testimony?

20 MR. THOMAS: Just Ethicon specific.

21 THE COURT: Make it clear that you only want an
 22 answer about Ethicon.

23 MR. THOMAS: Yes, sir.

24 THE COURT: Just this particular case.

25 (Sidebar concluded.)

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1 gentlemen, everybody is doing their job as best they see fit.
 2 I'll help out a little bit.

3 If you just answer the question and leave it to the
 4 lawyer who called you, if he thinks that something needs
 5 further explanation, he'll get back up on redirect and get
 6 back into it.

7 THE WITNESS: I understand.

8 THE COURT: All right.

9 MR. WALLACE: Thank you.

10 THE COURT: You're welcome.

11 MR. THOMAS: I need some help with the plaintiff's
 12 Power Point presentation. Can we go to page seven of the
 13 plaintiff's Power Point presentation, please?

14 BY MR. THOMAS:

15 Q. Dr. Guelcher, on the direct examination you were talking
 16 about, the title is Oxidation Alters the Structure of
 17 Polypropylene, and what you're explaining there is the
 18 chemical reaction between oxygen and polypropylene, correct?

19 A. That's right.

20 Q. And when you have oxidation impacting polypropylene, you
 21 have a change in molecular structure, don't you?

22 A. That's right.

23 Q. And you have a change in molecular weight, don't you?

24 A. That's right. It happens at the surface layer.

25 Q. You have a change in molecular weight, didn't you?

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1 A. Yes.

2 Q. And one of the ways that you measure the extent to which

3 a chemical -- strike that.

4 One of the ways that you measure the extent to which a

5 substance degrades or oxidizes is by a change in molecular

6 weight, true?

7 A. That's one way of measuring it, yes.

8 Q. Okay. And this oxidation that you've described in this

9 chemical structure is also intended to show that the

10 mechanical properties of the product can also change, correct?

11 A. Well, what's being shown here is just the chemical

12 reaction. I'm not sure what you mean.

13 Q. But the progression of that is, as you've testified on

14 direct examination, that you ultimately have a change in the

15 physical properties of that substance, correct?

16 A. Yes.

17 Q. Like tensile strength, correct?

18 A. That's true, yes.

19 Q. Or toughness, correct?

20 A. Yes.

21 Q. And so that you can actually measure, by analytical

22 chemistry and benchtop testing, the extent to which a

23 substance has undergone degradation as you've described it in

24 this slide, correct?

25 A. That's right. That's one way of measuring it.

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1 Q. Now, if you go to the next slide in this set, you're

2 talking about the implant materials selection. This

3 polypropylene, does the polypropylene in this slide, is this

4 Prolene?

5 A. No, this isn't Prolene; this is polypropylene.

6 Q. Okay. And we talked about before that Prolene without

7 antioxidants?

8 A. That's not Prolene.

9 Q. Exactly.

10 A. It's polypropylene.

11 Q. And as you add antioxidants to it, you do so to stabilize

12 the polypropylene, correct?

13 A. To get the oxidation, yes.

14 Q. And the reason why you do that is to extend the life of

15 the polypropylene for whatever it's being used for, correct?

16 A. That's right, yes.

17 MR. THOMAS: May I approach, Your Honor?

18 THE COURT: You may.

19 BY MR. THOMAS:

20 Q. Now, Dr. Guelcher, I've handed you what's been marked as

21 defendants' exhibit 30884 and this is a 1976 study called

22 Subcutaneous Implants of Polypropylene Filaments, first author

23 Liebert, correct?

24 A. Yes.

25 Q. And you're familiar with this paper, aren't you?

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1 A. I cited this paper in my report.

2 Q. And in the Liebert paper, the authors there tested

3 polypropylene without antioxidants against polypropylene with

4 antioxidants, correct?

5 A. They did, but they were different components, but they

6 did, yes.

7 Q. Thank you.

8 And if you go to page two of this exhibit, 3884.2, down

9 at the bottom it says, "The objectives of the study were

10 determined the length of time required for observable

11 degradation to occur, the type of degradation products formed,

12 the rate of degradation, and four, the effect of the presence

13 of an antioxidant on degradation and the rate of degradation."

14 Do you see that?

15 A. That's right. That's what it says.

16 Q. And what the Liebert article found was that there was no

17 oxidation of the polypropylene treated with antioxidants,

18 correct?

19 A. At 90 days they found that.

20 Q. Correct?

21 A. At 90 days, yes.

22 Q. And at paragraph five on the last page under conclusions,

23 the Liebert group concludes, "Infrared spectra and mechanical

24 testing of implanted and non-implanted filaments containing an

25 antioxidant show no changes in chemical or physical properties

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1 as a result of implantation." Correct?

2 A. I would agree with that statement up to 90 days.

3 Q. Thank you.

4 THE COURT: I'm sorry. You can't agree or disagree?

5 You have a partial agreement, is that right?

6 THE WITNESS: I have a partial -- I don't know how

7 much -- I don't want to step out of line again. I don't know

8 how much I can say.

9 THE COURT: All right. Okay.

10 THE WITNESS: Partial agreement is fair.

11 BY MR. THOMAS:

12 Q. Now, you are of the opinion that there is no antioxidant

13 package available that can effectively stabilize polypropylene

14 against the threat of oxidation, correct?

15 A. I believe that I said the antioxidants are depleted in

16 time, so that they don't last forever. I believe that's what

17 I said.

18 Q. Do you agree with the statement that I made?

19 A. Could you read it again?

20 Q. You are of the opinion that there is no antioxidant

21 package available that can effectively stabilize polypropylene

22 against the threat of oxidation.

23 A. I don't know of any. I guess I would agree. I don't

24 know of any that would.

25 Q. And you know what a peer-reviewed study is, don't you?

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1 A. Yes, I've published a lot of peer-reviewed studies.
 2 Q. And a peer-reviewed study is one that somebody writes and
 3 subjects to review by your peers before it's published,
 4 correct?
 5 A. That's how it works.
 6 Q. And in the 50 years that Prolene polypropylene has been
 7 used for implantation in humans, you're not aware of any
 8 peer-reviewed study which suggests that Ethicon Prolene loses
 9 its antioxidant package such that it oxidizes and becomes
 10 embrittled, are you?
 11 A. I've not seen that in a peer-reviewed study.
 12 Q. You don't have an opinion in this case about whether Mrs.
 13 Huskey's mesh degraded, do you?
 14 A. I believe it degraded based on the foreign body reaction,
 15 but I don't have the data, is that fair?
 16 Q. You don't know whether the mesh is brittle, do you?
 17 A. I've not tested it.
 18 Q. You don't know whether it's oxidized at all, do you?
 19 A. As I said, I believe it is, but I've not tested it
 20 because I don't have it.
 21 Q. That's because you don't have the material to test,
 22 correct?
 23 A. Yes, sir, that's right.
 24 Q. Let's go to page 10 of the Power Point presentation,
 25 please.

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1 THE WITNESS: I have not done it yet.
 2 BY MR. THOMAS:
 3 Q. Now, you talked about the seven-year dog study. There
 4 was no evidence of embrittlement in the sutures tested in the
 5 seven-year dog study, do you agree with that?
 6 A. Yes, there was no embrittlement reported in that study.
 7 Q. Thank you.
 8 A. Well, can I qualify it?
 9 Q. And there was no evidence of mechanical breakage in the
 10 seven-year dog study, correct?
 11 A. I believe on the surface there was evidence of
 12 embrittlement, but what you've asked me --
 13 Q. There's no evidence of mechanical breakage in the
 14 seven-year dog study?
 15 A. I do agree that there's no evidence of mechanical
 16 breakage.
 17 Q. And no evidence of loss of the mechanical properties of
 18 the sutures in the seven-year dog study, do you agree with
 19 that?
 20 A. Can I be specific? There was tensile strength,
 21 elongation and modulus, and those parameters were not changed.
 22 Well, they were changing, but --
 23 THE COURT: Can you answer the question?
 24 A. Those three prongs.
 25 Q. Thank you.

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1 Now, you talked to the jury at some length about this
 2 flow chart, the effect of the foreign body reaction on
 3 implants, and just so it's clear, what you depict here is not
 4 your experience with polypropylene, correct?
 5 A. What I show here is based on the experience with the
 6 pacemaker lead insulation and what I believe is happening to
 7 polypropylene.
 8 MR. THOMAS: Your Honor, move to strike. Ask him to
 9 answer the question.
 10 THE COURT: Sustained. The witness is directed to
 11 answer the question.
 12 THE WITNESS: Okay. Sorry. What's the question
 13 again?
 14 BY MR. THOMAS:
 15 Q. Dr. Guelcher, what you showed here is not related to your
 16 experience with polypropylene?
 17 A. Not my experience.
 18 Q. What you show here is your experience with polyether
 19 urethane, correct?
 20 A. It's not my experience. It's published experience, yes.
 21 Q. You've not done this analysis, testing it, analyzing it,
 22 published it, with respect to polypropylene, have you?
 23 A. No. But I'm in the process of doing that. I'm sorry.
 24 MR. THOMAS: Your Honor, move to strike.
 25 THE COURT: Sustained.

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1 MR. THOMAS: May I approach, Your Honor?
 2 THE COURT: You may.
 3 BY MR. THOMAS:
 4 Q. Dr. Guelcher, I'm handing you what's been marked as
 5 defendants' exhibit 23228.
 6 A. Yes.
 7 Q. And 23228 is entitled, Seven-Year Dog Study.
 8 A. Yes, I've seen this.
 9 Q. It's a bigger version of what you talked about on direct?
 10 A. Yes, sir.
 11 Q. Has more information than what we talked about on your
 12 direct examination, do you realize that?
 13 A. Yes. I've seen the entire study.
 14 Q. And the last three pages of that study are the mechanical
 15 properties testing conducted on the mesh after seven years,
 16 correct?
 17 A. Yes.
 18 Q. And it's this testing after seven years that showed that
 19 the mesh explanted from the dogs after seven years did not
 20 lose any of its physical properties, correct?
 21 A. I would not say it does not lose any of its physical
 22 properties. They measured strength, elongation and modulus.
 23 Q. For what they tested they didn't lose any of their
 24 physical properties, correct?
 25 A. For what they tested.

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- 1 Q. Is that true?
- 2 A. Yes.
- 3 Q. Thank you.
- 4 And also, if you go to page 115 -- are you at 115?
- 5 A. I'm at 115.
- 6 Q. Okay. Turn the page briefly. 116 is the area where you
- 7 testified to the jury about the conclusions, correct?
- 8 A. That's right.
- 9 Q. And it's conclusions under optical microscopy and
- 10 scanning electron microscopy, correct?
- 11 A. Right.
- 12 Q. And those would be visual observations of the test,
- 13 correct?
- 14 A. Well, it's scanning -- it's high magnification, it's
- 15 visual.
- 16 Q. It is visual, correct?
- 17 A. It is visual of the surface, yes.
- 18 Q. Well, Ethicon also conducted some analytical chemistry on
- 19 the mesh they explanted from the dogs too, didn't they?
- 20 A. They it.
- 21 Q. And if you go to page 115, they talk about GPC testing,
- 22 correct?
- 23 A. Yes.
- 24 Q. GPC testing is gel permeation chromatography, correct?
- 25 A. That's what it stands for.

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- 1 Q. And gel permeation chromatography measures molecular
- 2 weight, right?
- 3 A. That's right, measures molecular weight.
- 4 Q. And what the company found when it measured the molecular
- 5 weight after of these sutures after 17 years is that there was
- 6 no significant difference in molecular weight, correct?
- 7 A. A couples things. Not 17 years, seven years.
- 8 Q. I misspoke. Let me ask the question again so it's clear.
- 9 Isn't it true that the company reported on October 15, 1992
- 10 that the results of the gel permeation chromatography test run
- 11 on Prolene sutures explanted from dogs after seven years
- 12 showed no significant difference in molecular weight, correct?
- 13 A. That's the way they explain it, but there's not much
- 14 difference that's given there.
- 15 Q. Thank you.
- 16 Do you have the Wood article in front of you?
- 17 A. Yes, sir, I've got it right here.
- 18 Q. Wood?
- 19 A. Wood.
- 20 Q. The Wood article addressed hernia meshes, correct?
- 21 A. Yes, sir.
- 22 Q. It doesn't address Prolene polypropylene, does it?
- 23 A. It doesn't say Prolene, it says polypropylene.
- 24 Q. Okay. The Costello article.
- 25 A. Yes.

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- 1 Q. I'm sorry, I don't have the number in front of me. Do
- 2 you have the number?
- 3 A. Yes. It's 21468.
- 4 Q. The Costello article to which you referred on direct, if
- 5 you go to page two, that's a different mesh company
- 6 altogether, isn't it? It's a Bard mesh, see under materials
- 7 and methods?
- 8 A. It's a Bard mesh with a polypropylene component.
- 9 Q. Okay. But it's not Prolene polypropylene, is it?
- 10 A. It's not Prolene.
- 11 Q. Now, let's go to the Clavé article. Would you bring that
- 12 up, please? It's 21457.
- 13 If you go to the sixth page of that, under discussion?
- 14 A. Yes.
- 15 Q. Just the first paragraph under discussion, please.
- 16 A. I'm looking for it.
- 17 Q. It says, "The primary objectives of this study were to
- 18 objectively observe a series of prosthetic explants and to
- 19 characterize potential degradation which may occur in vivo."
- 20 Correct?
- 21 A. That's what it says.
- 22 Q. Those are the goals. And they did it by a number of
- 23 analytical chemistry tests, correct?
- 24 A. Yes.
- 25 Q. And if you go to the bottom right-hand corner of that

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- 1 same page, under several hypotheses, last paragraph? Can we
- 2 blow that up for the jury, please?
- 3 "Several hypotheses concerning the degradation of the
- 4 polypropylene are described below. None of these,
- 5 particularly direct oxidation, could be confirmed in this
- 6 study."
- 7 Did I read that correctly?
- 8 A. You read that correctly. That's the author's opinion.
- 9 Q. They're the ones that did the study, correct?
- 10 A. That doesn't mean I agree with that statement.
- 11 Q. Well, you've not done this study, have you?
- 12 A. No, but it's common to see papers --
- 13 Q. Okay. Thank you.
- 14 THE COURT: I cautioned you about argument. Let's
- 15 just stop arguing.
- 16 THE WITNESS: Okay. Sorry.
- 17 BY MR. THOMAS:
- 18 Q. Next page, please.
- 19 Under direct oxidation of the polypropylene, last
- 20 sentence.
- 21 A. Yes.
- 22 Q. FTIR is an analytical chemistry technique where you
- 23 determine the extent to which there's oxidation in
- 24 polypropylene, correct?
- 25 A. I spoke about that in my direct, yes.

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1 Q. And what you didn't speak about on direct is the last
 2 line of that paragraph that says, "The FTIR analysis neither
 3 confirmed nor excluded oxidation of polypropylene in the in
 4 vivo environment." Correct?
 5 A. Again, I don't share that opinion, but that's what they
 6 wrote.
 7 Q. That's what the people who did the testing said, correct?
 8 A. I don't want to argue.
 9 Q. Go to the next page, number eight. And on the right side
 10 they're doing DSC analysis, correct?
 11 A. Yes.
 12 Q. And DSC analysis is like a melting point type of analysis
 13 so you can determine whether the melting point of a substance
 14 changed to determine whether the chemical composition changes,
 15 correct?
 16 A. So DSC measures transitions in melting temperature and
 17 heat of fusion.
 18 Q. Okay. And you look under in this study, do you see this?
 19 "In this study, no difference between DSC thermograms of
 20 pristine and degraded samples was found. Additionally FTIR
 21 analysis did not conclusively confirm that the degradation was
 22 due to oxidation."
 23 Did I read that correctly?
 24 A. The FTIR -- yes, you read it correctly. The FTIR refers
 25 to the previous comment.

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1 Dr. Guelcher, just to refresh your recollection, you
 2 weren't asked about whether or not this article, the Clav
 3 article, which has a hundred explanted vaginal mesh devices,
 4 had any of the polypropylene as Prolene, were you?
 5 A. I was not asked that question.
 6 Q. And isn't it true that in this article Prolene was
 7 examined and degradation was found?
 8 THE COURT: Sustained. It is leading. I know it's
 9 tempting.
 10 MR. WALLACE: Very tempting, Your Honor.
 11 BY MR. WALLACE:
 12 Q. In examining the Clavé article, did you find that Prolene
 13 was a polypropylene mesh that was examined in this study?
 14 A. So on this same page it says the DSC thermograms of
 15 treated degraded and non-degraded LDPPMF explants were similar
 16 to those of treated Prolene soft. Additionally, the DSC
 17 thermograms of degraded --
 18 THE COURT: Could you slow down a bit?
 19 THE WITNESS: I can. Being a professor is hard, you
 20 talk too fast.
 21 The DSC thermograms of degraded and non-degraded
 22 HDPPMF explant were also similar to those of treated pristine
 23 Prolene samples.
 24 Q. Thank you. Let's move on in the article, Doctor. Let's
 25 move to page 270 and you'll probably see in your copy there is

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1 MR. THOMAS: Your Honor, may I have a moment?
 2 THE COURT: You may.
 3 MR. THOMAS: That's all the questions I have, Your
 4 Honor.
 5 THE COURT: Redirect.
 6 MR. WALLACE: Your Honor, may I proceed?
 7 THE COURT: You may.
 8 REDIRECT EXAMINATION OF SCOTT GUELCHER BY MR. WALLACE:
 9 Q. You were asked some questions by Mr. Thomas about the
 10 Costello article and the Wood article, and asked whether or
 11 not the polypropylene in those articles were Prolene. Do you
 12 remember that?
 13 A. Yes, sir.
 14 Q. But you weren't asked by Mr. Thomas about the Clav
 15 article and whether or not there was Prolene in that article.
 16 A. Yes.
 17 Q. Were you?
 18 A. No, I was not.
 19 Q. Can we pull up the images on page 265?
 20 LDPPMF, the one on the right.
 21 A. Yes.
 22 Q. Do you see that?
 23 A. This is not Clavé.
 24 Q. Yes, that's Wood. We'd like to put up Clavé. Let me
 25 give you the number. That is 21457.

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1 some things at the top of the page.
 2 A. Yes.
 3 Q. I'm going to refer you to the left-hand column beginning
 4 with the word polypropylene that's already highlighted. If
 5 you could highlight down to the bottom of the column there.
 6 A. Yes.
 7 Q. And I ask if you could read that first paragraph, please,
 8 and tell me whether or not Mr. Thomas asked you about that
 9 paragraph.
 10 A. "Polypropylene, in particular, LDPPMF, is the most used
 11 material in the PFD surgery. It is generally considered an
 12 inert material. This study contradicts this established fact
 13 and confirms the results of other studies on polypropylene
 14 materials used in other areas of medical specialization."
 15 I was not asked about this paragraph.
 16 Q. And with respect to the LDPPMF, is that what was referred
 17 to as the Prolene?
 18 A. From the previous page that I read, yes.
 19 Q. Thank you.
 20 And you were asked now -- well, you were asked about
 21 Clavé, Wood and Costello. Did each of those studies confirm
 22 degradation?
 23 MR. THOMAS: Objection, Your Honor. Asked and
 24 answered. Beyond the scope.
 25 THE COURT: I'm going to allow it. And it's leading.

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1 But I want to get.

2 THE WITNESS: In my direct examination I testified
3 that those papers point to degradation either through surface
4 cracking, changes in other types of properties. In my opinion
5 they all point to degradation.

6 BY MR. WALLACE:

7 Q. Did Mr. Thomas present you with one study that says --

8 THE COURT: Let's don't do argumentative stuff.

9 MR. WALLACE: I'm sorry, Your Honor.

10 Q. Did Mr. Thomas present you with any studies that say
11 pelvic floor mesh does not degrade?

12 A. He did not present me with any studies and I've not seen
13 any studies that state that.

14 Q. You were asked some questions about embrittlement on
15 cross examination. In your review of Ethicon documents, did
16 you see whether or not Ethicon did any research on its meshes
17 whatsoever for embrittlement?

18 A. I've not seen the studies in the meshes. The sutures
19 studies did point to embrittlement on the surface. And it
20 starts at the surface --

21 MR. THOMAS: Your Honor, object. It's
22 non-responsive.

23 THE COURT: First part of the answer is directly to
24 the question and may be considered by you. When the doctor
25 started going on, you're to ignore that.

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1 MR. THOMAS: Your Honor, I'm --

2 THE COURT: Can I see counsel?

3 (The following occurred at sidebar.)

4 THE COURT: Let me just shortcut this. I don't
5 recall him being asked about his experience with vaginal mesh.

6 MR. WALLACE: Sure. He was asked about his
7 experience with researching polypropylene and the work done in
8 this case. All I was simply pointing out is that he's been
9 asked to present at conferences regarding his research. So if
10 I phrase the question differently, I could do that and just
11 move on.

12 THE COURT: I don't quite know what you're doing.

13 MR. THOMAS: Your Honor, that's really getting into
14 the area that we're trying to avoid because if he has any
15 research at all, it's not in this case, it's in the other
16 cases. And if I'm going to cross examine him at all -- and
17 just for court's benefit, I know for a fact that he and his
18 co-expert, Dr. Dunn, have conducted extensive analytical
19 testing on other meshes. I could have gone into that at great
20 length because he didn't do the same kind of testing here, and
21 it's the same kind of issue. That's the kind of research that
22 he's doing that they're presenting at these conferences and I
23 just don't want to get into this.

24 THE COURT: Okay. Don't get us into a mess.

25 MR. WALLACE: Okay. I'll be very careful.

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1 THE WITNESS: My students do that, too.

2 BY MR. WALLACE:

3 Q. As a biomedical engineer that's offered opinions in this
4 case and the evidence you've reviewed and your experience
5 working on polypropylene mesh, do you think it's important for
6 a medical device manufacturer to test for embrittlement before
7 putting polypropylene mesh into women?

8 MR. THOMAS: Objection, Your Honor. Beyond the
9 scope.

10 THE COURT: I sustain it as beyond the scope.

11 BY MR. WALLACE:

12 Q. You were asked some questions about a plant at the
13 beginning of your cross examination. Do you recall that line
14 of questioning?

15 A. Yes, I do.

16 Q. Whether or not there's a clean plant, does that affect
17 your opinions in this case?

18 A. No. It just tells me that there's a reproducible way to
19 manufacture the material, that it's not changed.

20 Q. Does clean polypropylene degrade?

21 A. All polypropylene degrades.

22 Q. Have you -- you were asked some questions about your
23 experience with vaginal mesh. Have you given any scientific
24 presentations on vaginal mesh failures at any scientific
25 conferences?

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1 (Sidebar concluded.)

2 BY MR. WALLACE:

3 Q. Dr. Guelcher, I'm going to ask a very simple yes or no
4 question and I just want you to answer it yes or no without an
5 explanation.

6 Have you given any presentations to scientific peers on
7 the failure of vaginal mesh?

8 A. Have I given any? No.

9 Q. Well, let me ask, I'm going to give you your CV and ask
10 if I can refresh your recollection.

11 THE COURT: Yes, sir.

12 MR. THOMAS: I'll let him ask the question first.

13 BY MR. WALLACE:

14 Q. I'm going to direct you to page 18 of your CV, page 153.
15 I'd ask that you don't say anything else other than whether or
16 not you've given a presentation to scientific communities
17 about the failure of vaginal mesh.

18 MR. THOMAS: Your Honor, asked and answered. The
19 question is whether it refreshes his recollection.

20 THE COURT: I'll let him answer.

21 THE WITNESS: I'd like to explain my answer.

22 THE COURT: No.

23 THE WITNESS: It's --

24 THE COURT: No. Honestly, we're almost finished here
25 -- go ahead.

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1 THE WITNESS: I'm trying to do this the right way.
 2 BY MR. WALLACE:
 3 Q. Can you just answer yes or no? Have you ever given a
 4 presentation or gone or been invited to any conferences to
 5 speak on that issue?
 6 THE COURT: I overrule your objection. He may
 7 impeach his own witness.
 8 THE WITNESS: But there's a very simple 15-second
 9 explanation.
 10 THE COURT: I am telling you, if you don't answer
 11 this question directly, you're excused.
 12 THE WITNESS: No.
 13 BY MR. WALLACE:
 14 Q. You were asked some questions -- I've just got a couple
 15 more questions. You were asked some questions about FTIR
 16 tests and whether or not they could find degradation.
 17 A. Yes.
 18 Q. Are there limits to FTIR testing and whether or not
 19 that's a valid way to find degradation?
 20 A. FTIR probes, it measures the sample surface and also the
 21 interior, so you're typically measuring the entire volume and
 22 not specifically what happens at the surface.
 23 THE COURT: So I bet that's a yes.
 24 THE WITNESS: Yes.
 25 BY MR. WALLACE:

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1 Q. Have any of Mr. Thomas's questions changed your opinion
 2 in this case?
 3 A. No.
 4 MR. WALLACE: Thank you.
 5 THE COURT: All right. May the witness be excused
 6 from the trial? Or do you want him --
 7 MR. THOMAS: Yes, Your Honor.
 8 MR. WALLACE: Yes, sir.
 9 THE COURT: All right. Thank you very much, Doctor.
 10 Call your next witness.
 11 Doing all right, ladies and gentlemen? All right.
 12 MR. WALLACE: We're going to play the video
 13 deposition of Brigitte Helhammer, Your Honor.
 14 THE COURT: Ladies and gentlemen, the next testimony
 15 you will be presented with is by way of video deposition. As
 16 you've already heard from the lawyers, a deposition is sworn
 17 testimony. This particular testimony is taken and is done so
 18 under oath and you are to consider it as offered to you just
 19 the same as if that witness was sitting here today live.
 20 You're to give it no greater weight or no lesser weight
 21 because it's on TV.
 22 You may proceed.
 23 MR. WALLACE: Thank you, Your Honor.
 24 (The video testimony of Brigitte Helhammer was
 25 played.)

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1 MR. KUNTZ: Judge, that concludes the deposition of
 2 Brigitte Helhammer.
 3 THE COURT: All right. Call your next witness.
 4 MR. COMBS: Judge, there will be a very short defense
 5 cross examination.
 6 THE COURT: Okay. Well, let's do that.
 7 (The video testimony of Brigitte Helhammer
 8 continued.)
 9 MR. KUNTZ: Short redirect.
 10 THE COURT: Redirect.
 11 (The video testimony of Brigitte Helhammer
 12 continued.)
 13 THE COURT: All right. Thank you.
 14 Ladies and gentlemen of the jury, that concludes the
 15 videotaped testimony of this witness. You are to consider
 16 that testimony the same way you would as if the witness were
 17 here testifying. As to the technical quality of the video, I
 18 want to assure you that the lighting technician has been hired
 19 by Steven Spielberg and will not be available for later work.
 20 Call your next witness.
 21 MR. KUNTZ: Plaintiffs call Dr. Bruce Rosenzweig.
 22 BRUCE A. ROSENZWEIG, called as a witness, having been first
 23 duly sworn according to law, testified as follows:
 24 DIRECT EXAMINATION OF BRUCE A. ROSENZWEIG BY MR. KUNTZ:
 25 Q. Please state your name for the record.

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1 A. Bruce Alan Rosenzweig.
 2 Q. And are you a physician?
 3 A. Yes, I am.
 4 Q. What kind of doctor are you?
 5 A. My specialty is gynecology and my subspecialty is
 6 urogynecology.
 7 Q. Please describe to the jury your medical training and
 8 experience.
 9 A. I went to the University of Michigan for medical school.
 10 After that I did a postgraduate residency program in
 11 obstetrics and gynecology. Following that -- which is a four
 12 year residency. I spent one year after that doing what's
 13 called a pelvic surgery fellowship, which is an advanced
 14 pelvic surgery. And then I did a two-year fellowship in
 15 urogynecology.
 16 Q. Are you licensed to practice medicine?
 17 A. Yes, sir.
 18 Q. What states?
 19 A. I have an active license in the state of Illinois.
 20 Q. What teaching positions have you held?
 21 A. Currently I'm an assistant professor at in obstetrics and
 22 gynecology at Rush University Medical Center.
 23 Q. Have you published any articles related to the treatment
 24 of stress urinary incontinence?
 25 A. Yes, I have.

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1 Q. And when was that?

2 A. October of 2004.

3 Q. And where did that training take place?

4 A. In Liege, Belgium.

5 Q. And did that training with the TVT-O take place with Dr.

6 de Leval, the inventor of the product?

7 A. That is correct.

8 Q. And you were invited by Ethicon and they paid for you to

9 go over to Belgium and train with Dr. de Leval?

10 A. That is also correct.

11 Q. Tell us a little bit about that training class over in

12 Belgium.

13 A. Well, it was a three-day course. The first day was in a

14 classroom where we had didactic lectures. The second day we

15 spent in a cadaver laboratory where we got to do dissections

16 to show the area where the tape was going to go anatomically,

17 and also on a cadaver actually place the tape. And then the

18 third day we spent in the operating room with Dr. de Leval and

19 I had the opportunity of placing the tape in two live

20 patients.

21 THE COURT: All right. It's five o'clock. I'm quite

22 certain this witness will take more than just a few more

23 minutes. We're going to recess for the day.

24 Thank you, Doctor, you may step down.

25 Ladies and gentlemen of the jury, that concludes the

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1 (A recess was taken at 5:03 p.m.)

2 - - - - -

3

4 REPORTERS' CERTIFICATE

5

6 Carol Farrell, CRR, RMR, CCP, RPR, Official Court

7 Reporter of the United States District Court for the Southern

8 District of West Virginia, and Anthony Rolland, CRR, RMR, RPR,

9 do hereby certify that the foregoing is a true and accurate

10 transcript, to the best of our ability, of the proceedings as

11 taken stenographically by and before us at the time, place,

12 and on the date hereinbefore set forth.

13

14

15 /S/ Carol Farrell, CRR, RMR, CCP, RPR 08/25/2014

16 _____

17 Court Reporter Date

18 /S/ Anthony Rolland, CRR, RMR, RPR 08/25/2014

19 _____

20 Court Reporter Date

21

22

23

24

25

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1 testimony for today. We will -- you can go ahead, Doctor.

2 We'll start again in the morning right at 9:00

3 o'clock. I appreciate your promptness. We'll begin on time.

4 I missed it by ten minutes this morning, I'm not going to miss

5 it tomorrow.

6 Very important. Don't watch TV, local news, don't

7 read the newspaper, local newspaper. You can read the New

8 York Times or something like that. You can watch the national

9 news. If you want to stay happy, just don't watch the news,

10 it's depressing.

11 You're not to listen to, read anything about, see

12 anything, do any research about, use any social media, talk to

13 anyone about, answer any questions about this case.

14 Everything that you're allowed to do about this case you're

15 allowed to do right in here. Don't discuss it with anyone or

16 among yourselves. Have a very pleasant evening and I'll see

17 you right at 9:00 o'clock.

18 You're excused.

19 Counsel, do you want to stay a minute?

20 (The Jury left the courtroom at 5:02 p.m.)

21 THE COURT: Anything you need me for?

22 I appreciate the nice professional relationship

23 between counsel and the way this is going. Keep it up. See

24 you tomorrow morning.

25 MR. KUNTZ: Thank you, Your Honor.

EXHIBIT F

Scott Guelcher

Page 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC
REPAIR SYSTEM PRODUCTS
LIABILITY LITIGATION

THIS DOCUMENT RELATES TO THE
FOLLOWING CASES IN WAVE 1 OF
MDL 200:

Marty Babcock v. Ethicon, Inc.
Civil Action No. 2:12-cv-01052

[Complete caption below]

)
)
)
)
)
)Master File No.
)2:12-MD-02327
) MDL 2327
)
)JOSEPH R. GOODWIN
)U.S. DISTRICT
)JUDGE
)

DEPOSITION OF

SCOTT GUELCHER

Taken on behalf of the Defendants

March 23, 2016

8:51 a.m.

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

Scott Guelcher

Page 2	Page 4
<p>1 UNITED STATES DISTRICT COURT 2 SOUTHERN DISTRICT OF WEST VIRGINIA 3 AT CHARLESTON 4 IN RE: ETHICON, INC., PELVIC) 5 REPAIR SYSTEM PRODUCTS) 6 LIABILITY LITIGATION) 7) 8 THIS DOCUMENT RELATES TO THE)Master File No. 9 FOLLOWING CASES IN WAVE 1 OF)2:12-MD-02327 10 MDL 200:) MDL 2327 11) 12 Marty Babcock v. Ethicon, Inc.)JOSEPH R. GOODWIN 13 Civil Action No. 2:12-cv-01052)U.S. DISTRICT 14)JUDGE 15 Daphne Barker, et al. v.) 16 Ethicon, Inc., et al.) 17 Civil Action No. 2:12-cv-00899) 18) 19 Dorothy Baugher v. Ethicon,) 20 Inc., et al.) 21 Civil Action No. 2:12-cv-01053) 22) 23 Harriet Beach v. Ethicon,) 24 Inc., et al.) Civil Action No. 2:12-cv-00476) Myra Byrd, et al. v. Ethicon,) Inc., et al.) Civil Action No. 2:12-cv-00748) Fran Denise Collins v.) Ethicon, Inc., et al.) Civil Action No. 2:12-cv-00931) Dennis W. Dixon, Estate of) Virginia M. Dixon,) Deceased v. Ethicon, Inc., et al.) Civil Action No. 2:12-cv-01081) Lois Durham, et al. v.) Ethicon, Inc., et al.) Civil Action No. 2:12-cv-00760) Karen Forester, et al. v.) Ethicon, Inc., et al.)</p>	<p>1 Beverly Kivel v. Ethicon,) 2 Inc., et al.) 3 Civil Action No. 2:12-cv-00591) 4) 5 Cheryl Lankston v. Ethicon,) 6 Inc., et al.) 7 Civil Action No. 2:12-cv-00755) 8) 9 Heather Long v. Ethicon, Inc.,) 10 et al.) 11 Civil Action No. 2:12-cv-01275) 12) 13 Donna Massey, et al. v.) 14 Ethicon, Inc., et al.) 15 Civil Action No. 2:12-CV-00880) 16) 17 Angela Morrison, et al. v.) 18 Ethicon, Inc., et al.) 19 Civil Action No. 2:12-cv-00800) 20) 21 Maria Eugenia Quijano v.) 22 Ethicon, Inc., et al.) 23 Civil Action No. 2:12-cv-00799) 24) Penny Rhynehart v. Ethicon,) Inc., et al.) Civil Action No. 2:12-cv-01119) Victoria Rock v. Ethicon,) Inc., et al.) Civil Action No. 2:12-cv-00867) Denise Sacchetti v. Ethicon,) Inc., et al.) Civil Action No. 2:12-cv-01148) Debra A. Schnering, et al. v.) Ethicon, Inc., et al.) Civil Action No. 2:12-cv-01071) Sheri Scholl, et al. v.) Ethicon, Inc.) Civil Action No. 2:12-cv-00738) Donna Shepherd v. Ethicon,) Inc., et al.) Civil Action No. 2:12-cv-00967)</p>
Page 3	Page 5
<p>1 Shirley Freeman, et al. v.) 2 Ethicon, Inc., et al.) 3 Civil Action No. 2:12-cv-00490) 4) 5 Monica Freitas, et al. v.) 6 Ethicon, Inc., et al.) 7 Civil Action No. 2:12-cv-01146) 8) 9 Susan Guinn v. Ethicon, Inc.,) 10 et al.) 11 Civil Action No. 2:12-cv-01121) 12) 13 Wendy Hagans v. Ethicon, Inc.,) 14 et al.) 15 Civil Action No. 2:12-cv-00783) 16) 17 Beth Harter, et al. v. Ethicon,) 18 Inc., et al.) 19 Civil Action No. 2:12-cv-00737) 20) 21 Rocio Herrera-Nevarez v.) 22 Ethicon, Inc., et al.) 23 Civil Action No. 2:12-cv-01294) 24) Mary Holzerland, et al. v.) Ethicon, Inc., et al.) Civil Action No. 2:12-cv-00875) Lois Hoy, et al. v. Ethicon,) Inc., et al.) Civil Action No. 2:12-cv-00876) Myndal Johnson v. Ethicon,) Inc., et al.) Civil Action No. 2:12-cv-00498) Holly Jones, et al. v. Ethicon,) Inc., et al.) Civil Action No. 2:12-cv-00443) Debra Lynn Joplin v. Ethicon,) Inc., et al.) Civil Action No. 2:12-cv-00787) Margaret Kirkpatrick v.) Ethicon, Inc., et al.) Civil Action No. 2:12-cv-00746)</p>	<p>1 Cindy Smith v. Ethicon, Inc.,) 2 et al.) 3 Civil Action No. 2:12-cv-01149) 4) 5 Cherise Springer, et al. v.) 6 Ethicon, Inc., et al.) 7 Civil Action No. 2:12-cv-00997) 8) 9 Margaret Stubblefield v.) 10 Ethicon, Inc., et al.) 11 Civil Action No. 2:12-cv-00842) 12) 13 Lisa Thompson, et al. v.) 14 Ethicon, Inc., et al.) 15 Civil Action No. 2:12-cv-01199) 16) 17 Mary Thurston, et al. v.) 18 Ethicon, Inc., et al.) 19 Civil Action No. 2:12-cv-00505) 20) 21 Shirley Walker, et al. v.) 22 Ethicon, Inc., et al.) 23 Civil Action No. 2:12-cv-00873) 24) Cathy Warlick v. Ethicon,) Inc., et al.) Civil Action No. 2:12-cv-00276) Laura Waynick, et al. v.) Ethicon, Inc., et al.) Civil Action No. 2:12-cv-01151) Rebecca Wheeler, et al. v.) Ethicon, Inc., et al.) Civil Action No. 2:12-cv-01088) Nancy Williams v. Ethicon,) Inc., et al.) Civil Action No. 2:12-cv-00511) Thelma Wright v. Ethicon,) Inc., et al.) Civil Action No. 2:12-cv-01090) 23 24</p>

2 (Pages 2 to 5)

Scott Guelcher

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<p>1 APPEARANCES</p> <p>2</p> <p>3 FOR THE PLAINTIFFS:</p> <p>4 Michael H. Bowman, Esquire</p> <p>5 Wexler Wallace LLP</p> <p>6 55 West Monroe Street, Suite 3300</p> <p>7 Chicago, Illinois 60603</p> <p>8 312.346.2222</p> <p>9 mhb@wexlerwallace.com</p> <p>10</p> <p>11 FOR THE DEFENDANTS:</p> <p>12 Chad R. Hutchinson, Esquire</p> <p>13 Butler Snow, LLP</p> <p>14 1020 Highland Colony Parkway, Suite 1400</p> <p>15 Ridgeland, Mississippi 39157</p> <p>16 601.948.5711</p> <p>17 chad.hutchinson@butlersnow.com</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1</p> <p>2 QUESTIONS INSTRUCTED NOT TO ANSWER</p> <p>3</p> <p>4 PAGE</p> <p>5 I understand that. But I'm -- my question 96</p> <p>6 is related to these 44 women. Can you tell</p> <p>7 us, to a reasonable degree of scientific</p> <p>8 certainty, whether or not the mesh, in any</p> <p>9 of these 44 women, ever oxidized?</p> <p>10</p> <p>11 I'm asking, Doctor, can it ever 162</p> <p>12 be completely -- can oxidation ever be</p> <p>13 completely eliminated?</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
Page 7	Page 9
<p>1 EXAMINATION</p> <p>2</p> <p>3 PAGE</p> <p>4 Examination by Mr. Hutchinson 9</p> <p>5</p> <p>6 EXHIBITS</p> <p>7</p> <p>8 PAGE</p> <p>9 Exhibit 1 Notice to Take Deposition 9</p> <p>10 Exhibit 2 Expert Report of Scott Guelcher, 10</p> <p>11 Ph.D., CV, Billing Information,</p> <p>12 Reliance List</p> <p>13 Exhibit 3 Abstract - Oxidative Degradation 28</p> <p>14 of Polypropylene</p> <p>15 Pelvic Mesh in Vitro</p> <p>16 Exhibit 4 Characterization of the host 44</p> <p>17 inflammatory</p> <p>18 response following implantation</p> <p>19 of prolapse</p> <p>20 mesh in rhesus macaque</p> <p>21 Exhibit 5 Blank Piece of Paper 113</p> <p>22 Exhibit 6 In vivo oxidative degradation of 130</p> <p>23 polypropylene pelvic mesh - Imel</p> <p>24 Exhibit 7 Seven Year Dog Study 166</p> <p>Exhibit 8 Stress-Strain Curve - Graph 179</p>	<p>1 SCOTT GUELCHER</p> <p>2 was called as a witness, and after having been</p> <p>3 first duly sworn, testified as follows:</p> <p>4</p> <p>5 (Whereupon Exhibit 1 was marked as an</p> <p>6 exhibit.)</p> <p>7</p> <p>8 EXAMINATION BY MR. HUTCHINSON:</p> <p>9 Q. Good morning, Dr. Guelcher. Chad</p> <p>10 Hutchinson, counselor for Ethicon.</p> <p>11 I'll hand you what we've marked as</p> <p>12 Exhibit 1 to your deposition. Have you seen that</p> <p>13 deposition notice before?</p> <p>14 A. Yes.</p> <p>15 Q. And did you bring any documents with</p> <p>16 you responsive to that deposition notice?</p> <p>17 A. I did not.</p> <p>18 MR. HUTCHINSON: Counsel, I understand</p> <p>19 you're producing a flash drive right now, more or</p> <p>20 less as we speak, that will contain what?</p> <p>21 MR. BOWMAN: It will contain everything</p> <p>22 he reviewed, and it is on his reliance list.</p> <p>23 MR. HUTCHINSON: And it will not</p> <p>24 contain any new testing; is that correct?</p>

3 (Pages 6 to 9)

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<p>1 MR. BOWMAN: There -- the testing</p> <p>2 that's been done has been produced in the past.</p> <p>3 There's nothing new produced today.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Dr. Guelcher, what are the names of the</p> <p>6 products that you're -- you're here to give</p> <p>7 testimony about?</p> <p>8 A. I believe the SUI slings and the POP</p> <p>9 devices that would include the GYNEMESH, the TVT,</p> <p>10 TVT-O, is my understanding. I have to look at my</p> <p>11 report for all the list of the names.</p> <p>12 Q. Sure. And I'll hand you what we'll</p> <p>13 mark as Exhibit 2 to your deposition.</p> <p>14 A. Okay.</p> <p>15 (Whereupon Exhibit 2 was marked as an</p> <p>16 exhibit.)</p> <p>17 THE WITNESS: That would help me.</p> <p>18 MR. HUTCHINSON: Sure. Counsel.</p> <p>19 MR. BOWMAN: Thank you.</p> <p>20 THE WITNESS: Did you -- is there still</p> <p>21 a question?</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. Yes, sir.</p> <p>24 A. Oh.</p>	<p>1 Q. What does TVT-S stand for?</p> <p>2 A. That's the -- the shorter sling, so</p> <p>3 the -- the -- the TVT is a longer sling. The TVT-S</p> <p>4 is shorter.</p> <p>5 Q. Okay. And what does TVT-S stand for?</p> <p>6 A. I -- I don't remember the meaning</p> <p>7 behind the acronym right now. The TVT is a</p> <p>8 transvaginal tape, but I don't -- I don't -- I</p> <p>9 don't remember exactly what the S stands for right</p> <p>10 now.</p> <p>11 Q. Which -- which POP or pelvic organ</p> <p>12 prolapse devices are you here to give testimony</p> <p>13 about? Which specific ones?</p> <p>14 A. Well, they're listed in the report, the</p> <p>15 PROSIMA, the PROLIFT, and the GYNEMESH.</p> <p>16 Q. Any others?</p> <p>17 A. Those are the ones I can think of right</p> <p>18 now.</p> <p>19 Q. What about PROLIFT+M? Are you here to</p> <p>20 give testimony today about PROLIFT+M?</p> <p>21 A. Yes. The PROLIFT+M is also mentioned</p> <p>22 in the report. That -- well -- okay. It's -- it's</p> <p>23 a hybrid material that has the -- the MONOCRYL</p> <p>24 polyester resin with the PROLENE. So that's in the</p>
Page 11	Page 13
<p>1 Q. I'm waiting for your answer.</p> <p>2 A. Oh.</p> <p>3 Well, as I stated in my report, these</p> <p>4 are the SUI, stress urinary incontinence, and the</p> <p>5 pelvic organ prolapse, POP, devices. This would</p> <p>6 include PROSIMA, PROLIFT, GYNEMESH, the TVT</p> <p>7 devices. All of these devices are made from</p> <p>8 PROLENE.</p> <p>9 Q. All right. Which specific SUI slings</p> <p>10 are you here to give testimony about?</p> <p>11 A. There's 200 cases in this wave. My</p> <p>12 understanding is some of these are TVT, TVT-O.</p> <p>13 Those are the ones I can remember right now.</p> <p>14 My report was directed more toward the</p> <p>15 polypropylene, PROLENE, polypropylene that's used</p> <p>16 to make those devices.</p> <p>17 Q. TVT and TVT-O are the only two names of</p> <p>18 the products that you can remember for SUI devices?</p> <p>19 A. There's a -- I'm sorry. There's a</p> <p>20 TVT-S. Those are the ones that I can remember</p> <p>21 right now.</p> <p>22 Q. Okay. Can you remember any others?</p> <p>23 A. I think that's what I can remember</p> <p>24 right now.</p>	<p>1 report as well.</p> <p>2 Q. And, Doctor, you're referring to</p> <p>3 Exhibit 2, which is your expert report; is that</p> <p>4 correct?</p> <p>5 A. I am.</p> <p>6 Q. Is this report complete and accurate?</p> <p>7 A. Yes.</p> <p>8 Q. Is this a final version?</p> <p>9 A. Yes. I -- I -- I believe so.</p> <p>10 Q. How many hours did you spend on this</p> <p>11 report?</p> <p>12 A. I -- I don't know. I don't -- I don't</p> <p>13 track the hours. I don't -- I don't know how many</p> <p>14 hours I spent.</p> <p>15 Q. Okay. How do you bill the attorneys</p> <p>16 for your time?</p> <p>17 A. So that was a -- a billing sheet that I</p> <p>18 believe I produced with the report, where we just</p> <p>19 bill by the report. And this was, I believe, a --</p> <p>20 what I would call a medium report.</p> <p>21 Q. What is a medium report?</p> <p>22 A. It's -- in the billing, I just break it</p> <p>23 down and do a short report, a medium, and a long</p> <p>24 report. This one would have been in the medium</p>

Scott Guelcher

Page 14	Page 16
<p>1 category.</p> <p>2 Q. So would that be a flat fee for this</p> <p>3 report?</p> <p>4 A. That's correct.</p> <p>5 Q. What is the flat fee for this report</p> <p>6 that --</p> <p>7 A. It's \$10,000. Yeah.</p> <p>8 Q. Marked as Exhibit 2?</p> <p>9 A. That's correct.</p> <p>10 Q. And are all -- are all of the opinions</p> <p>11 that you intend to offer in this litigation</p> <p>12 contained in your expert report marked as Exhibit</p> <p>13 2?</p> <p>14 A. Yes, they are.</p> <p>15 Q. I've handed you, also, a CV, which is</p> <p>16 part of Exhibit 2.</p> <p>17 A. Yes.</p> <p>18 Q. Is that the most recent version of your</p> <p>19 CV?</p> <p>20 A. I believe so. I have to check it</p> <p>21 briefly. But I believe this is the -- this is the</p> <p>22 current version. Okay. Yes.</p> <p>23 Q. And your reliance list is also marked</p> <p>24 as Exhibit 2. Is that the most current reliance</p>	<p>1 with Dr. Iakovlev. I -- I wrote the paper with</p> <p>2 him, but. . . I guess I'm a little confused about</p> <p>3 the question.</p> <p>4 Q. Okay. So the question is I want you to</p> <p>5 talk about your opinions as they relate to pelvic</p> <p>6 organ prolapse products.</p> <p>7 A. Yes.</p> <p>8 Q. Have you discussed those opinions with</p> <p>9 anybody other than Dr. Dunn and Dr. Iakovlev?</p> <p>10 A. Not other than attorneys, I can't</p> <p>11 think. . .</p> <p>12 Q. Never spoken to any other scientist or</p> <p>13 medical doctor about those opinions; is that</p> <p>14 correct?</p> <p>15 A. So I -- I have presented at -- at</p> <p>16 meetings, the IUGA meeting last year in Nice.</p> <p>17 Q. And we're going to get to that --</p> <p>18 A. Okay.</p> <p>19 Q. -- but I want to talk about your</p> <p>20 opinions as they relate to pelvic organ prolapse</p> <p>21 products.</p> <p>22 A. Okay.</p> <p>23 Q. Have you discussed those with any</p> <p>24 scientist or medical doctor?</p>
Page 15	Page 17
<p>1 list?</p> <p>2 A. I believe so. Again, I'd like to check</p> <p>3 it for just a second. I believe so.</p> <p>4 Q. Okay. Doctor, other than attorneys,</p> <p>5 have you discussed your opinions, as they relate to</p> <p>6 pelvic organ -- pelvic organ prolapse products,</p> <p>7 with anyone else?</p> <p>8 A. With -- Dr. Dunn and I have been</p> <p>9 working together on this litigation with the</p> <p>10 attorneys.</p> <p>11 Q. And other than Dr. Dunn, have you</p> <p>12 discussed your opinions regarding pelvic organ</p> <p>13 prolapse products with anyone else?</p> <p>14 A. No. I'm sorry. Dr. Iakovlev.</p> <p>15 (Reporter interruption for</p> <p>16 clarification.)</p> <p>17 THE WITNESS: I'm sorry. Dr. Iakovlev,</p> <p>18 I-a-k-o-v-l- -- do you mean -- can I clarify? Do</p> <p>19 you mean in this specific report the opinions --</p> <p>20 like this --</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. (Indicating yes.)</p> <p>23 A. Are you talking about this specific</p> <p>24 report or -- yeah. I've not discussed this report</p>	<p>1 A. At the meeting there was some</p> <p>2 discussion among the meeting participants. But --</p> <p>3 Q. Was this -- excuse me.</p> <p>4 A. Sorry. Go ahead. Yeah.</p> <p>5 Q. Was this that meeting in France?</p> <p>6 A. Yeah. That's right.</p> <p>7 Q. Other than in France, have you ever</p> <p>8 discussed any of those opinions with anyone else?</p> <p>9 A. I've presented it at a meeting at -- at</p> <p>10 the American Institute of Chemical Engineers in the</p> <p>11 fall of 2014. Presented a talk there.</p> <p>12 Q. Your opinions as they relate to pelvic</p> <p>13 organ prolapse products?</p> <p>14 A. I don't -- you know, I don't know that</p> <p>15 we had the POPs in that talk. I think that was</p> <p>16 slings.</p> <p>17 Q. Okay.</p> <p>18 A. So we talked about polypropylene</p> <p>19 oxidation.</p> <p>20 Q. I understand that.</p> <p>21 A. Not necessarily about the POP devices.</p> <p>22 Q. Okay.</p> <p>23 A. I'm just trying to understand what</p> <p>24 you're asking.</p>

5 (Pages 14 to 17)

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<p>1 Q. Fair enough. My question, though, as</p> <p>2 it relates to pelvic organ prolapse products, have</p> <p>3 you discussed those opinions as they relate to</p> <p>4 pelvic organ prolapse products with anyone else?</p> <p>5 A. I -- I don't believe so.</p> <p>6 Q. Doctor, have you -- have you ever told</p> <p>7 any doctor at Vanderbilt that you have concerns</p> <p>8 about the safety of polypropylene or PROLENE mesh?</p> <p>9 A. I had some email correspondence with a</p> <p>10 Vanderbilt OB/GYN. I had some -- we -- it wasn't</p> <p>11 about -- it wasn't about opinions about the</p> <p>12 products. It was about research on polypropylene</p> <p>13 oxidation. But I haven't discussed my opinions</p> <p>14 with them.</p> <p>15 Q. Okay. Do you know how many doctors</p> <p>16 practice medicine at Vanderbilt?</p> <p>17 A. No.</p> <p>18 Q. Have you ever told a doctor at</p> <p>19 Vanderbilt that you believe PROLENE mesh degrades</p> <p>20 via oxidation?</p> <p>21 A. No. I haven't had the opportunity.</p> <p>22 Q. Doctor, you -- your lawyers -- or a</p> <p>23 lawyer sitting to the right of you is producing me</p> <p>24 a flash drive with all the documents you have</p>	<p>1 Q. (Indicating yes.)</p> <p>2 A. Okay.</p> <p>3 Q. Do you -- do you remember that? It was</p> <p>4 in September of 2015.</p> <p>5 A. Yes. I think that's the last time I</p> <p>6 was here.</p> <p>7 Q. In fact, you were in the same seat.</p> <p>8 A. Probably. I don't -- I don't remember.</p> <p>9 Q. Do you remember -- have you been</p> <p>10 deposed in any mesh litigation since September of</p> <p>11 2015?</p> <p>12 A. I don't believe so.</p> <p>13 Q. Have you testified in any trials</p> <p>14 regarding mesh litigation since 2000 -- since</p> <p>15 September 2015?</p> <p>16 A. There was a Boston Scientific trial in</p> <p>17 Statesville, North Carolina, in October.</p> <p>18 Q. And you testified live in that trial?</p> <p>19 A. Live?</p> <p>20 Q. (Indicating yes.)</p> <p>21 A. Yes.</p> <p>22 Q. Are you still active in the</p> <p>23 professional societies of American Institute of</p> <p>24 Chemical Engineers?</p>
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<p>1 reviewed; is that correct?</p> <p>2 A. That's right.</p> <p>3 Q. And would those be internal Ethicon</p> <p>4 documents, at least some of them?</p> <p>5 A. Some of them are. Yeah.</p> <p>6 Q. Have you ever signed a confidentiality</p> <p>7 agreement with respect to the documents that you've</p> <p>8 reviewed from Ethicon?</p> <p>9 A. I can't remember. Probably. I don't</p> <p>10 remember.</p> <p>11 Q. Where would it be if you did?</p> <p>12 A. I don't know. I don't know that I have</p> <p>13 that agreement.</p> <p>14 Q. Where would you look for it if you had</p> <p>15 it?</p> <p>16 A. Well, I would think the attorneys would</p> <p>17 have it. I -- I don't -- I just don't know that</p> <p>18 I've ever signed it.</p> <p>19 Q. Do you remember being deposed in the</p> <p>20 Mullins litigation?</p> <p>21 A. Mullins?</p> <p>22 Q. Mullins. It's the -- was -- it was 37</p> <p>23 consolidated --</p> <p>24 A. It was consolidated in West Virginia?</p>	<p>1 A. Yes, I am.</p> <p>2 Q. The Society for Biomaterials?</p> <p>3 A. Yes.</p> <p>4 Q. Research Society For Bone and Joint</p> <p>5 Injectable Biomaterials?</p> <p>6 A. Yes.</p> <p>7 Q. I noticed that your expert report,</p> <p>8 which is marked as Exhibit 2, doesn't include those</p> <p>9 professional societies. Why not?</p> <p>10 A. They're listed on my CV, which is part</p> <p>11 of the report. I -- I don't know why. I just</p> <p>12 didn't list them.</p> <p>13 Q. Doctor, do you recall -- did you ever</p> <p>14 read the deposition transcript from the Mullins</p> <p>15 litigation?</p> <p>16 A. I don't remember. I've -- I just don't</p> <p>17 remember.</p> <p>18 Q. Have any of your opinions changed since</p> <p>19 you were deposed in the Mullins litigation?</p> <p>20 A. No.</p> <p>21 Q. What has been your total billing amount</p> <p>22 that you have billed plaintiff attorneys since the</p> <p>23 Mullins litigation?</p> <p>24 A. Oh, in this particular case. I</p>

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<p>1 submitted a bill for the report, for 10,000 for the 2 medium report. 3 Q. What about any charges for your time? 4 A. For this litigation? I don't think so. 5 Oh. No. This -- this is the only -- that was the 6 only one for this litigation. 7 Q. Have you done any additional work since 8 the Mullins deposition regarding mesh? 9 A. What do you mean by "work"? Do you 10 mean testing or reading? I'm not sure what you 11 mean. 12 Q. Well, any other work that you believe 13 is applicable to the mesh litigation since you were 14 deposed in Mullins in September 2015. 15 A. I -- I've not done any -- any testing. 16 I've done more reading, research. But I've not 17 done any testing since that time. 18 Q. What additional research have you done? 19 A. Reviewing the newer papers that were in 20 the report, reviewing the -- the Ethicon internal 21 documents, that sorts of activities. 22 Q. The "newer papers" that you're 23 referring to, are those contained in your expert 24 report?</p>	<p>1 this question because it's a research project. 2 It's not part of these opinions in the litigation. 3 So it's -- I would call that a research project. 4 Q. Is it a research project for 5 litigation? 6 A. Not necessarily. 7 Q. So who is sponsoring the research 8 project? 9 A. Well, this is part of the work, as an 10 academic, is finding funding to support the work, 11 so. . . I don't -- I don't have any funding for it 12 right now. 13 Q. Okay. Are you -- but you're trying to 14 get funding for a research project? 15 A. I'm considering it, but I haven't done 16 anything definitive at this time. 17 Q. Have you asked anybody specifically for 18 funding? 19 A. No. 20 Q. Have you asked any plaintiff lawyer for 21 funding of this research project? 22 A. No. 23 Q. Can you give me just a general idea of 24 the research project that you're contemplating?</p>
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<p>1 A. I believe they are. Yes. That would 2 be -- yes, they are. 3 Q. Have you published any additional 4 articles? 5 A. On polypropylene mesh? 6 Q. (Indicating yes.) 7 A. No. 8 Q. Do you have any pending? 9 A. No. 10 Q. Have you worked on any since? 11 A. No. 12 Q. The last paper that you authored 13 regarding mesh was the one with Dr. Iakovlev 14 entitled "Degradation of Polypropylene in Vivo"? 15 A. Yes. 16 Q. Doctor, as we sit here today, are you 17 planning on doing any additional testing of mesh? 18 A. I don't know at this time. There are 19 no definite plans. 20 Q. Are you considering any additional 21 testing of mesh? 22 A. I am. 23 Q. All right. What are you considering? 24 A. Well, I don't -- I can't really answer</p>	<p>1 A. I'm really not comfortable doing that. 2 Just -- I -- I need to -- I just -- I don't -- I 3 don't think that would be good. 4 Q. Okay. Are you refusing to tell me? 5 A. "Refusing" is kind of a strong word. I 6 mean, I -- I don't want to discuss it in this 7 deposition. It's a research project that's outside 8 this litigation. So I -- to me it's not 9 something -- 10 Q. Does it -- 11 A. -- I -- I -- I would like to discuss 12 here. 13 Q. Does it relate to PROLENE mesh? 14 A. I don't know. I haven't -- I don't 15 know at this time. 16 Q. Does it relate to any of Ethicon's 17 products? 18 A. Again, at this time, I -- I don't know. 19 Q. Okay. 20 A. I haven't gotten that far. 21 Q. We talked about the IUGA meeting that 22 you went to in France -- 23 A. Yes. 24 Q. -- back in -- in the summer of last</p>

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<p>1 year; is that correct?</p> <p>2 A. That's right.</p> <p>3 Q. Have you attended any other</p> <p>4 professional meetings since then regarding mesh?</p> <p>5 A. Regarding mesh? No. Not that I can</p> <p>6 remember.</p> <p>7 Q. Were you ever reimbursed for your time</p> <p>8 going to France for this meeting by the plaintiffs'</p> <p>9 lawyers?</p> <p>10 A. No.</p> <p>11 Q. Did anybody ever compensate you for</p> <p>12 your time?</p> <p>13 A. So I -- I paid for my expenses</p> <p>14 through -- through a fund I have at Vanderbilt that</p> <p>15 I use for international travel.</p> <p>16 Q. There was some discussion, if I recall,</p> <p>17 about you submitting a research grant to the</p> <p>18 National Institution of Health regarding mesh with</p> <p>19 a Dr. Carey; do you remember that?</p> <p>20 A. Yes. And for the record, can I just --</p> <p>21 when you asked previously about who I have talked</p> <p>22 with, she would be one that I discussed -- I just</p> <p>23 forgot until you brought it up. Okay? I just --</p> <p>24 Q. That's fine.</p>	<p>1 Q. Were you talking to her about doing</p> <p>2 anything as it relates to mesh?</p> <p>3 A. I just don't remember what I talked to</p> <p>4 her about. It's been awhile, and I haven't really</p> <p>5 acted on it. So I just -- I have lots of</p> <p>6 discussions about new research projects. I -- I</p> <p>7 just don't remember.</p> <p>8 (Whereupon Exhibit 3 was marked as an</p> <p>9 exhibit.)</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. I understand. I'll hand you what we've</p> <p>12 marked as Exhibit 3 to your deposition.</p> <p>13 A. Okay.</p> <p>14 Q. This is the -- the paper that you</p> <p>15 presented on at the meeting in France; is that</p> <p>16 right?</p> <p>17 A. Let me review it for -- briefly.</p> <p>18 This -- this -- yes, this appears to be that</p> <p>19 abstract that I submitted to the IUGA, and then I</p> <p>20 presented on it at the IUGA meeting.</p> <p>21 Q. And what contribution did Dr. Dunn</p> <p>22 make?</p> <p>23 A. So Dr. Dunn did the FTIR and the SEM</p> <p>24 analysis. He and his student.</p>
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<p>1 A. Yeah. For the record, Dr. Carey would</p> <p>2 be another person that I've talked with.</p> <p>3 Q. Okay. You can answer that question --</p> <p>4 A. I'm sorry. Okay. Ask the question</p> <p>5 again. I -- I -- I forgot.</p> <p>6 Q. You discussed an idea about submitting</p> <p>7 a research grant to the NIH regarding mesh with</p> <p>8 Dr. Carey; do you remember that?</p> <p>9 A. Vaguely. Yeah, I think it came up.</p> <p>10 Q. What is -- what was the topic?</p> <p>11 A. I don't remember.</p> <p>12 Q. What's the status of it?</p> <p>13 A. I haven't submitted anything.</p> <p>14 Q. Okay. But what's the status of it?</p> <p>15 A. What do you mean the status? Like --</p> <p>16 Q. Where does it stand?</p> <p>17 A. Well, as I was saying earlier, I just</p> <p>18 haven't been working on it and I haven't drafted</p> <p>19 anything. I haven't submitted anything. I</p> <p>20 just. . .</p> <p>21 Q. Was this the same research grant idea</p> <p>22 that we discussed earlier?</p> <p>23 A. I don't remember. I -- I don't</p> <p>24 remember what I was talking with her about doing.</p>	<p>1 Q. And what did -- what contributions were</p> <p>2 yours?</p> <p>3 A. So my contributions were more on the</p> <p>4 design of the experiment, the selection of the</p> <p>5 oxidative medium, the -- those would have been my</p> <p>6 contributions.</p> <p>7 Q. Do you have any current or pending</p> <p>8 experience with -- experiments with Dr. Dunn?</p> <p>9 A. I do not.</p> <p>10 Q. What about Dr. Iakovlev?</p> <p>11 A. I do not.</p> <p>12 Q. Do you have any current or pending</p> <p>13 experiments regarding mesh with anyone, as we sit</p> <p>14 here today?</p> <p>15 A. No. I do not.</p> <p>16 Q. Do you have any mesh explants in your</p> <p>17 custody or control?</p> <p>18 A. No.</p> <p>19 Q. What about any pristine mesh exemplars</p> <p>20 in your custody or control?</p> <p>21 A. No.</p> <p>22 Q. You don't have any mesh whatsoever</p> <p>23 available to you in your custody or control?</p> <p>24 A. No.</p>

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<p>1 Q. Do you still defer to Dr. Dunn on the</p> <p>2 interpretations of the FTIR spectra?</p> <p>3 A. I do.</p> <p>4 Q. And you disclosed this work in the</p> <p>5 Perry litigation, didn't you? That was for TVT</p> <p>6 ABBREVO?</p> <p>7 A. The ABBREVO would be another product.</p> <p>8 Yes.</p> <p>9 Q. And you attempted to rely on this paper</p> <p>10 in the Perry litigation, didn't you?</p> <p>11 MR. BOWMAN: Object to form.</p> <p>12 THE WITNESS: I -- I just don't</p> <p>13 remember. It may have been on the -- on the -- on</p> <p>14 the reliance list, but I don't -- I know it came up</p> <p>15 in the deposition, but I deferred to Dr. Dunn for</p> <p>16 the experimental details in the deposition. That's</p> <p>17 what I remember.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. Did you rely on this, Doctor, in</p> <p>20 forming your opinions in the Perry litigation</p> <p>21 regarding TVT ABBREVO?</p> <p>22 A. I don't believe so. I mean, my</p> <p>23 opinions have not changed in some time. So this</p> <p>24 was supplemental information that supported my</p>	<p>1 These were sutures. I -- I -- we did -- no. No.</p> <p>2 This was mesh. This was -- this was mesh. I -- I</p> <p>3 don't remember the actual product that we were -- I</p> <p>4 mean, it's been some time. I think there was a --</p> <p>5 I think there was -- I think it was -- there were</p> <p>6 definitely two Boston Scientific meshes, maybe the</p> <p>7 Pinnacle. There were slings. Maybe the TV -- I</p> <p>8 think the TVT, too.</p> <p>9 Q. So you used a TVT and a Pinnacle device</p> <p>10 in your work --</p> <p>11 A. Perhaps --</p> <p>12 Q. -- regarding oxidative degradation of</p> <p>13 polypropylene in pelvic mesh in vivo attached as --</p> <p>14 I mean, marked as Exhibit 3 to your deposition? Is</p> <p>15 that your testimony, sir?</p> <p>16 A. That's what I remember. I didn't -- I</p> <p>17 mean, I wasn't -- yeah, I wasn't -- I'd have to</p> <p>18 review this. But I believe it was a TVT and two</p> <p>19 Boston Scientific meshes that were included -- I</p> <p>20 just need to read -- can I read this again?</p> <p>21 Because I can't remember, you know, exactly --</p> <p>22 Q. Absolutely.</p> <p>23 A. This was written two years ago</p> <p>24 almost --</p>
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<p>1 opinion, but -- and it was on the reliance list</p> <p>2 but -- I think it was. I just -- I can't remember</p> <p>3 the details.</p> <p>4 Q. Doctor, you relied on this work, that</p> <p>5 we've marked as Exhibit 3 to your deposition, in</p> <p>6 the Winebarger versus Boston Scientific litigation;</p> <p>7 is that correct?</p> <p>8 A. Winebarger? What product was this? I</p> <p>9 can't remember the names -- the plaintiff name.</p> <p>10 Q. It was a lawsuit styled Winebarger,</p> <p>11 W-i-n-b-a-r-g-e-r, versus Boston Scientific.</p> <p>12 A. That name just doesn't sound -- was it</p> <p>13 part of a wave? Was it -- I just don't remember</p> <p>14 the plaintiffs' names probably.</p> <p>15 Q. Do you recall relying on this work that</p> <p>16 was marked as Exhibit 3 in the Winebarger versus</p> <p>17 Boston Scientific litigation?</p> <p>18 A. I don't. Because I don't recall the</p> <p>19 litigation. I just -- I don't -- the -- the</p> <p>20 plaintiff's name is -- that doesn't sound familiar</p> <p>21 to me.</p> <p>22 Q. Okay. Doctor, when we look at Exhibit</p> <p>23 3, what product was used in your work?</p> <p>24 A. It's been some time. I don't remember.</p>	<p>1 Q. Absolutely.</p> <p>2 A. -- so I'm trying to remember exactly</p> <p>3 what I wrote.</p> <p>4 Q. And this was also presented a year ago,</p> <p>5 correct?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. So if you'll read through it and</p> <p>8 tell me, sir, what the name of the products were</p> <p>9 that were used in this experiment.</p> <p>10 A. Okay. I can -- give me a minute</p> <p>11 to. . .</p> <p>12 Okay. So this was the mesh study.</p> <p>13 Again, it's not stated in the abstract, but -- let</p> <p>14 me just look at it again. (Reviews document.)</p> <p>15 Okay. I -- I believe it was the TVT</p> <p>16 and the Boston Scientific Advantage and Links,</p> <p>17 maybe. It's just been so long, I -- I can't</p> <p>18 remember the exact devices.</p> <p>19 Q. So the products that you used were from</p> <p>20 two different manufacturers, in this abstract; is</p> <p>21 that correct, sir?</p> <p>22 A. I believe so.</p> <p>23 Q. Was the TVT mechanically cut or laser</p> <p>24 cut?</p>

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<p>1 A. I don't remember.</p> <p>2 Q. How can you find out?</p> <p>3 A. Dr. Dunn would have all that</p> <p>4 information. He -- he had the mesh. He put it in</p> <p>5 the medium. He was the one that physically did the</p> <p>6 work. He and, I think, maybe one of his students</p> <p>7 did some of it, but he -- he's the one that had the</p> <p>8 exemplars and cut the samples and put them in the</p> <p>9 medium. I didn't do that. And so --</p> <p>10 Q. Okay.</p> <p>11 A. And I never had the mesh in my</p> <p>12 possession that I remember.</p> <p>13 Q. Oh, you didn't. So, Doctor, can you</p> <p>14 testify, to a reasonable degree of scientific</p> <p>15 certainty, that the two products that were used in</p> <p>16 this experiment were TVT and a Boston Scientific</p> <p>17 product?</p> <p>18 MR. BOWMAN: Object to form.</p> <p>19 THE WITNESS: Again, I'm going based on</p> <p>20 my memory.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. I understand.</p> <p>23 A. And --</p> <p>24 Q. But I'd like for -- I'd like -- I need</p>	<p>1 working on it. We don't know what we're going to</p> <p>2 do yet. It's just -- you know, we have -- very</p> <p>3 busy, and it's -- I don't -- I don't know what the</p> <p>4 plan is. But I'm not relying on it because we</p> <p>5 haven't published it.</p> <p>6 Q. Okay. Any other reasons?</p> <p>7 A. No. That's the main reason. I -- I</p> <p>8 believe the Court likes to see published studies</p> <p>9 and that's --</p> <p>10 Q. Okay.</p> <p>11 A. -- that -- that's our plan.</p> <p>12 Q. But it's fair to say that you've</p> <p>13 written a paper that investigated oxidative</p> <p>14 degradation of polypropylene mesh in vitro using an</p> <p>15 oxidative medium and you're not relying on that</p> <p>16 work in this litigation?</p> <p>17 MR. BOWMAN: Object to form.</p> <p>18 THE WITNESS: Can you repeat that? I'm</p> <p>19 sorry.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Yes.</p> <p>22 A. It was long.</p> <p>23 Q. It's fair to say that you've written a</p> <p>24 paper --</p>
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<p>1 an answer, based upon a reasonable degree of</p> <p>2 scientific certainty. Can you testify today, to a</p> <p>3 reasonable degree of scientific certainty,</p> <p>4 regarding the specific names of the products used</p> <p>5 in this experiment?</p> <p>6 A. I mean, I believe, to a reasonable</p> <p>7 degree of scientific certainty, that's what we --</p> <p>8 that's what we used. That's what I remember. You</p> <p>9 know, I work closely with Dr. Dunn. Our offices</p> <p>10 are right beside each other. So, I mean, he --</p> <p>11 he -- that's what I believe he did.</p> <p>12 Q. Okay. And, Doctor, when you were</p> <p>13 deposed in September in the Mullins litigation, you</p> <p>14 didn't rely on this abstract for your opinions in</p> <p>15 that; is that correct?</p> <p>16 A. I don't believe so.</p> <p>17 Q. And you're not relying on the abstract</p> <p>18 that you published for your opinions in this</p> <p>19 litigation; is that correct?</p> <p>20 A. No, I'm not.</p> <p>21 Q. Okay. Why not?</p> <p>22 A. Well, we -- we -- we would like to</p> <p>23 publish it. And that's something -- that's part of</p> <p>24 what we're -- we -- we just -- we're -- we're</p>	<p>1 A. Okay.</p> <p>2 Q. -- that investigated oxidative</p> <p>3 degradation of polypropylene using an oxidated</p> <p>4 medium and you're not relying on it in this</p> <p>5 litigation; is that fair to say?</p> <p>6 A. I would say it's a submitted abstract.</p> <p>7 This is a submitted abstract. I wouldn't call this</p> <p>8 a paper. It's a published abstract, and it is peer</p> <p>9 reviewed but not like a paper. It's not -- I'm not</p> <p>10 relying on it.</p> <p>11 Q. And --</p> <p>12 A. And that -- go ahead.</p> <p>13 Q. What is the status of this work,</p> <p>14 Doctor?</p> <p>15 A. As I said, I -- I -- I don't know. We</p> <p>16 don't know what we're going to do with it yet.</p> <p>17 Q. When is the last time you talked to</p> <p>18 Dr. Dunn about this?</p> <p>19 A. I don't remember.</p> <p>20 Q. Has it been more than six months?</p> <p>21 A. Probably not. But I just don't -- I</p> <p>22 don't remember what we said about this. We</p> <p>23 haven't -- I haven't relied on it in the recent</p> <p>24 litigation in some time. And it's -- you know,</p>

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<p>1 it's just one of these unpublished studies that we</p> <p>2 did, published an abstract, submitted at a meeting,</p> <p>3 and just haven't followed up on it for the paper.</p> <p>4 That's what I would say.</p> <p>5 Q. Is this work finished?</p> <p>6 A. Well, this study is finished. But when</p> <p>7 you were asking me about research earlier, I -- I</p> <p>8 mean, I -- I'm trying to be honest without</p> <p>9 revealing, you know, what I consider to be, you</p> <p>10 know, associated with my research being</p> <p>11 confidential. But I don't know what we're going to</p> <p>12 do next.</p> <p>13 Q. Okay. But this study was finished,</p> <p>14 correct?</p> <p>15 A. This study is completed. Yes.</p> <p>16 Q. Right. And this study was peer</p> <p>17 reviewed in an abstract in the International</p> <p>18 Urogynecology Journal, correct?</p> <p>19 MR. BOWMAN: Object to form.</p> <p>20 THE WITNESS: It was -- it was reviewed</p> <p>21 for the meeting. I -- I wouldn't -- it's not --</p> <p>22 yes, it was reviewed. Okay.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. And, Doctor, were the chemical</p>	<p>1 A. I think I just answered the question.</p> <p>2 Q. You didn't.</p> <p>3 A. I did.</p> <p>4 Q. I need "yes" or "no," and then you can</p> <p>5 answer. . .</p> <p>6 A. I can't give you a yes or no because</p> <p>7 I -- I feel like you're trying to put -- I need to</p> <p>8 be very specific about what that medium is</p> <p>9 simulating.</p> <p>10 Q. Absolutely.</p> <p>11 And my question to you, sir, is the</p> <p>12 oxidative medium designed to represent the actual</p> <p>13 in vivo conditions in the body? Yes or no?</p> <p>14 A. But "actual in vivo conditions" is what</p> <p>15 I'm hung up on. That's a very vague term. It</p> <p>16 is -- it's meant to simulate the</p> <p>17 microenvironment -- in vivo microenvironment that</p> <p>18 the material is exposed to. That's what it's meant</p> <p>19 to simulate. That's, I think, an answer to your</p> <p>20 question. You're asking me -- that's my answer.</p> <p>21 Q. Is that the best you can do?</p> <p>22 A. That's the best I can do. I'm sorry.</p> <p>23 I just -- I don't want to agree to some very</p> <p>24 vaguely stated question.</p>
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<p>1 conditions, to which you subjected the mesh,</p> <p>2 intended to represent an actual in vivo condition</p> <p>3 in the body?</p> <p>4 A. So they were intended to simulate the</p> <p>5 adherent macrophage pocket, the -- the space</p> <p>6 between the adherent cell and the surface of the</p> <p>7 material.</p> <p>8 Q. I under --</p> <p>9 A. That's been published. Right? Yeah.</p> <p>10 Q. I understand. But was it intended to</p> <p>11 represent actual in vivo conditions in the body?</p> <p>12 Yes or no?</p> <p>13 A. Well, I thought I answered your</p> <p>14 question. That would be the -- the -- it's</p> <p>15 simulating that -- that situation where you have an</p> <p>16 inherent macrophage attached to a biomaterial in</p> <p>17 the body and there's a privileged microenvironment</p> <p>18 between the cell and the material. And that medium</p> <p>19 has been shown to -- published to simulate those</p> <p>20 oxidative conditions between the cell and the</p> <p>21 surface of the material.</p> <p>22 Q. Are the chemical conditions intended to</p> <p>23 represent actual in vivo conditions in the body,</p> <p>24 sir? Yes or no?</p>	<p>1 Q. Doctor, do you write about in vivo</p> <p>2 conditions in this abstract?</p> <p>3 A. I'd have to read it again. (Reviews</p> <p>4 document.)</p> <p>5 Q. Let's look on the last page.</p> <p>6 A. Okay.</p> <p>7 Q. At the conclusion. "Oxidative</p> <p>8 degradation of polypropylene pelvic mesh was</p> <p>9 evidenced by chemical and physical changes under</p> <p>10 simulated in vivo conditions."</p> <p>11 A. Okay.</p> <p>12 Q. Did you write that?</p> <p>13 A. I wrote that.</p> <p>14 Q. Okay. So my question to you, sir, are</p> <p>15 the chemical conditions, to which you subjected the</p> <p>16 mesh, intended to represent simulated in vivo</p> <p>17 conditions in the body? Yes or no?</p> <p>18 A. Yes. I wrote that. I stand by what I</p> <p>19 wrote.</p> <p>20 Q. All right. Since the Mullins</p> <p>21 deposition, Doctor, have you done any work to</p> <p>22 determine if oxidized polypropylene will stain?</p> <p>23 A. Since the Mullins deposition last fall?</p> <p>24 Q. Yes, sir.</p>

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<p>1 A. No.</p> <p>2 Q. Have you ever done any work in your</p> <p>3 life to determine if oxidized polypropylene will</p> <p>4 stain?</p> <p>5 A. No.</p> <p>6 Q. When is the last time you've spoken</p> <p>7 with Dr. Iakovlev?</p> <p>8 A. That's been some time. Maybe -- I need</p> <p>9 to think for a minute. Probably last summer at the</p> <p>10 meeting.</p> <p>11 Q. Doctor, are you aware of any literature</p> <p>12 that discusses the extent to which oxidized</p> <p>13 polypropylene traps and holds stain?</p> <p>14 A. Well, we discussed it in the paper with</p> <p>15 Dr. Iakovlev, but I -- I'm not aware, at this</p> <p>16 moment, off the top of my head, of another paper</p> <p>17 that would -- I'd have to look at the paper again.</p> <p>18 It's been some time.</p> <p>19 Q. You testified in the Mullins deposition</p> <p>20 that you've never done an XPS analysis. Does that</p> <p>21 remain true?</p> <p>22 A. I'd like to -- I've -- I've never</p> <p>23 physically done it myself. My students have done</p> <p>24 it. But I've never actually done the measurement.</p>	<p>1 any molecular weight testing of PROLENE?</p> <p>2 A. Well, I'm trying to -- I'm trying to</p> <p>3 answer. So -- I mean, I don't -- I mean, being a</p> <p>4 professor, I don't actually work in the lab. I</p> <p>5 have graduate students and a lab manager that do</p> <p>6 the work that we discuss, right? And I -- I'm --</p> <p>7 sort of direct of work, if you want to call it</p> <p>8 that.</p> <p>9 And what I -- what I was saying is that</p> <p>10 some time ago, a couple years at least, we --</p> <p>11 Dr. Dunn and I sent some samples to -- Dr. Dunn</p> <p>12 handled the samples -- to another laboratory to do</p> <p>13 molecular weight measurements. And whether PROLENE</p> <p>14 meshes -- you know, meshes made out of PROLENE were</p> <p>15 in those samples, I can't remember. It's been a</p> <p>16 long time. So. . .</p> <p>17 Q. Okay. And you don't know the results;</p> <p>18 is that correct?</p> <p>19 A. I don't remember the results.</p> <p>20 Q. Doctor, have you ever done any</p> <p>21 molecular weight testing of PROLENE explants?</p> <p>22 A. I don't think so. The samples -- no, I</p> <p>23 don't think so.</p> <p>24 (Whereupon Exhibit 4 was marked as an</p>
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<p>1 Q. Have you ever done any molecular weight</p> <p>2 testing of PROLENE?</p> <p>3 A. Not of PROLENE.</p> <p>4 Oh, I'm sorry. Can I --</p> <p>5 Q. (Indicating yes.)</p> <p>6 A. We -- we did some molecular weight</p> <p>7 testing with Dr. Dunn on exemplars some time ago.</p> <p>8 It's been a long time. And I don't remember if</p> <p>9 PROLENE or TVT devices were included. I can't</p> <p>10 remember the devices.</p> <p>11 Q. Okay.</p> <p>12 A. But we -- we sent those to another lab.</p> <p>13 It was in one of his reports.</p> <p>14 Q. What were the results?</p> <p>15 A. I don't remember. I haven't been</p> <p>16 relying on that, so I just don't remember.</p> <p>17 (Reporter interruption for</p> <p>18 clarification.)</p> <p>19 THE WITNESS: You know, I'm. . .</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Well, my question --</p> <p>22 A. Yeah.</p> <p>23 Q. I'm not sure I understood your answer.</p> <p>24 Have you ever done -- have you personally ever done</p>	<p>1 exhibit.)</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Doctor, handing you what we'll mark as</p> <p>4 Exhibit 4 to your deposition --</p> <p>5 A. Okay.</p> <p>6 Q. -- you cite this on page 9 of your</p> <p>7 expert report. Do you remember that?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And, in fact, if you look on</p> <p>10 your expert report, under "Summary of Opinions,"</p> <p>11 Number 7.</p> <p>12 A. Okay.</p> <p>13 Q. It's on page 3. It states --</p> <p>14 A. Okay.</p> <p>15 Q. -- ". . .the use of heavy-weight meshes</p> <p>16 directly correlates with more exposure of</p> <p>17 polypropylene to the Foreign Body Reaction and</p> <p>18 greater changes after implantation. . ."</p> <p>19 Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. All right. Doctor, how do you define</p> <p>22 "heavy-weight"?</p> <p>23 A. My understanding is that the TVT mesh</p> <p>24 has a weight of around -- a surface density of</p>

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<p>1 around 100, would be a heavy-weight mesh.</p> <p>2 Let me look at this paper again for a</p> <p>3 minute. I believe it was discussed in here, the</p> <p>4 densities of the specific meshes that she tested.</p> <p>5 Yeah. So this would be the GYNEMESH</p> <p>6 that had a density of 44 grams to square meter;</p> <p>7 ULTRAPRO, which was 31; and Restorelle was 19.</p> <p>8 Q. Doctor, how do you define</p> <p>9 "heavy-weight"?</p> <p>10 A. How do I define "heavy-weight"?</p> <p>11 Q. Yes, sir.</p> <p>12 A. I think -- I think something greater</p> <p>13 than 50 grams per square meter would be a heavier</p> <p>14 weight mesh.</p> <p>15 Q. And how do you come up with the number</p> <p>16 50 grams per square meter?</p> <p>17 A. I -- I can't remember. There's some</p> <p>18 papers -- there's a paper where this is -- these</p> <p>19 are classified, and I just can't remember the</p> <p>20 numbers right now.</p> <p>21 Q. Well, you mean you can't remember the</p> <p>22 cite right now?</p> <p>23 A. Yeah. Well, the -- I can't remember</p> <p>24 the citation, and I can't remember the actual</p>	<p>1 right? I mean, as the density increases, it's</p> <p>2 going to be more intense. That's what I was</p> <p>3 saying.</p> <p>4 Q. Right. My question to you, sir, is how</p> <p>5 do you define a heavy-weight mesh? Is it something</p> <p>6 greater than 50 -- I'm sorry -- something greater</p> <p>7 than a 100 grams per meter squared? Is that</p> <p>8 Dr. Guelcher's definition?</p> <p>9 MR. BOWMAN: Object to form.</p> <p>10 THE WITNESS: Again, there's lots of</p> <p>11 different definitions of polypropylene mesh. 100</p> <p>12 grams per square meter is -- I would consider that</p> <p>13 to be a heavy-weight mesh.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Okay. And if something is less than</p> <p>16 100 grams per square metered, would that be a</p> <p>17 medium-weight mesh or a light-weight mesh? What</p> <p>18 would it be?</p> <p>19 A. I don't -- I don't know specifically.</p> <p>20 I mean, everybody has a different range that they</p> <p>21 use to define that. I don't -- I mean, there's not</p> <p>22 a lot of -- there's not a lot of agreement in the</p> <p>23 literature.</p> <p>24 Q. You can't tell me whether or not</p>
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<p>1 ranges that were listed in the -- in the table.</p> <p>2 I'd have to look at this --</p> <p>3 Q. I understand. But, Doctor, sitting</p> <p>4 here today, and one of your opinions on Number 7 is</p> <p>5 the -- is about heavy-weight meshes. So my</p> <p>6 question to you is --</p> <p>7 A. Okay.</p> <p>8 Q. -- how do you define a heavy-weight</p> <p>9 mesh?</p> <p>10 A. So a heavy-weight mesh would be a mesh</p> <p>11 in the range of -- I'd probably say 100 grams per</p> <p>12 square meter. Those are the heavy-weight meshes</p> <p>13 that -- in my recollection.</p> <p>14 Q. Okay. And if something is less than</p> <p>15 100 grams per square meter, according to your --</p> <p>16 your definition, would that be a light-weight mesh?</p> <p>17 A. No. I don't think I would call it a</p> <p>18 light-weight mesh. I mean, what I was really</p> <p>19 trying to say in this opinion is that the more</p> <p>20 polypropylene is there, the more intense the</p> <p>21 foreign body reaction. That's what the point of</p> <p>22 that opinion is.</p> <p>23 Q. Right. But my --</p> <p>24 A. So it's a sliding scale. I mean --</p>	<p>1 something would be a light-weight mesh if it was</p> <p>2 less than 100 grams per meter squared; is that</p> <p>3 correct?</p> <p>4 A. Some would call that a -- a</p> <p>5 light-weight mesh --</p> <p>6 Q. All right.</p> <p>7 A. -- if it's less than 100.</p> <p>8 Q. Do you -- do you, Doctor, as a polymer</p> <p>9 scientist and as an expert in this litigation, have</p> <p>10 a definition for a light-weight mesh?</p> <p>11 A. No. Because I was looking at it from</p> <p>12 the perspective of the amount of polypropylene</p> <p>13 increases with mesh density. It's not just a</p> <p>14 simple classification, as the mesh increases, the</p> <p>15 foreign body reaction increases, because it's</p> <p>16 dependent on that surface of polypropylene. That's</p> <p>17 what I'm saying.</p> <p>18 Q. Are you aware of any medical device</p> <p>19 industry standard that measures or defines</p> <p>20 heavy-weight mesh?</p> <p>21 A. Industry standard? I -- I'm -- I -- I</p> <p>22 think that's what I was saying. There's different</p> <p>23 investigators and maybe companies who have</p> <p>24 defined -- but it's -- it's not -- I don't -- I</p>

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<p>1 don't -- I guess what I'm saying is I don't</p> <p>2 consider it a -- something that's agreed upon, say,</p> <p>3 like in an ASTM standard. It's somewhat</p> <p>4 discretionary, I would say.</p> <p>5 Q. All right. So you're not aware of any</p> <p>6 medical device industry standard that measures or</p> <p>7 defines heavy-weight mesh; is that correct?</p> <p>8 A. There may be a standard that mesh -- I</p> <p>9 can't think of it right now. I -- I can't</p> <p>10 remember.</p> <p>11 Q. Okay. Doctor, are you aware of any</p> <p>12 medical device industry standard that measures and</p> <p>13 defines pore size?</p> <p>14 A. I mean, pore size isn't really what I</p> <p>15 was talking about in my opinions. So that's not</p> <p>16 something --</p> <p>17 Q. All right. I can cut to the chase.</p> <p>18 A. Okay.</p> <p>19 Q. Do you have any opinions whatsoever</p> <p>20 regarding the pore size of the PROLENE mesh</p> <p>21 contained in any of the products that you're giving</p> <p>22 opinions about today?</p> <p>23 MR. BOWMAN: Object to form.</p> <p>24 BY MR. HUTCHINSON:</p>	<p>1 discussing pore size in the report.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Okay. Well, Doctor, what is your</p> <p>4 opinion regarding the ideal weight of mesh?</p> <p>5 A. I don't believe I've expressed an</p> <p>6 opinion about the ideal weight. My opinion has</p> <p>7 been the more mesh, the more intense the foreign</p> <p>8 body reaction. So I haven't really expressed an</p> <p>9 opinion about ideal weight.</p> <p>10 Q. Okay. Do you have an opinion, as we</p> <p>11 sit here today, regarding the ideal mesh -- mesh in</p> <p>12 terms of weight?</p> <p>13 A. It would help me if you could be</p> <p>14 specific. I -- I -- I'm not saying that there's an</p> <p>15 ideal weight for the mesh. All I'm saying is that</p> <p>16 the intensity of the foreign body reaction</p> <p>17 increases with the weight density of the mesh.</p> <p>18 That's -- and I'm not saying that that should be 30</p> <p>19 or it should be 20. I'm saying that -- it's -- as</p> <p>20 the amount of polypropylene increases, the</p> <p>21 intensity of foreign body reaction. That's --</p> <p>22 that's what I'm saying.</p> <p>23 Q. Okay. But can you tell us -- can you</p> <p>24 tell us the ideal weight of the mesh?</p>
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<p>1 Q. We can short circuit that.</p> <p>2 A. Okay. Let me just think for a second.</p> <p>3 So I -- I don't believe that I</p> <p>4 discussed pore size in my report.</p> <p>5 Q. Is it fair to say, Doctor, you have no</p> <p>6 opinions regarding pore size of the mesh of the</p> <p>7 products that you're here to give testimony about</p> <p>8 today; is that right?</p> <p>9 MR. BOWMAN: Object to form.</p> <p>10 THE WITNESS: Maybe other than it could</p> <p>11 change in the mechanical environment and in the</p> <p>12 chemical changes that happen to the mesh, pore size</p> <p>13 could change, that could affect infiltration.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Is that an opinion you're going to</p> <p>16 stand by today?</p> <p>17 A. I don't believe so. It's not in my</p> <p>18 report.</p> <p>19 Q. Okay. Thank you.</p> <p>20 So fair so say you have no opinions</p> <p>21 regarding pore size on the products that you're</p> <p>22 designated to give testimony about today?</p> <p>23 MR. BOWMAN: Object to form.</p> <p>24 THE WITNESS: I think so. I'm not</p>	<p>1 A. No. I've not testified about an ideal</p> <p>2 weight of mesh.</p> <p>3 Q. Doctor, you'll agree that any implanted</p> <p>4 material will elicit some form of foreign body</p> <p>5 reaction or inflammatory response?</p> <p>6 A. Yes. That's a foreign body reaction.</p> <p>7 When a material is implanted, it induces and</p> <p>8 elicits a foreign body reaction.</p> <p>9 Q. And the microphage's response is an</p> <p>10 essential component of tissue incorporation,</p> <p>11 correct?</p> <p>12 A. What do you mean by "essential"? I'm</p> <p>13 not --</p> <p>14 Q. You must have a microphage response to</p> <p>15 have tissue incorporation in the mesh, correct?</p> <p>16 A. Well, macrophages infiltrate the mesh</p> <p>17 like they do any foreign body. It just happens.</p> <p>18 It's not -- it's not necessarily something that can</p> <p>19 be controlled. It just happens. It's a foreign</p> <p>20 body reaction.</p> <p>21 Q. Let's look at the Moalli paper --</p> <p>22 A. Okay.</p> <p>23 Q. -- that we've marked --</p> <p>24 A. Okay.</p>

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<p>1 Q. -- Exhibit 4. Are you there with me?</p> <p>2 A. I am.</p> <p>3 Q. This paper studied two meshes with</p> <p>4 PROLENE: GYNEMESH PS and ULTRAPRO; is that right?</p> <p>5 A. Yes. I believe so.</p> <p>6 Q. And this is the one of the newer papers</p> <p>7 that you're relying on; is that correct?</p> <p>8 A. It is.</p> <p>9 Q. What does GYNEMESH PS stand for?</p> <p>10 A. I -- I don't remember the PS. I know</p> <p>11 that the GYNEMESH is -- is -- I believe it's used</p> <p>12 in the POP kits. It's a lower-density mesh than</p> <p>13 the TVT. I don't know what the PS -- I'd have to</p> <p>14 look at the paper again. I don't. . .</p> <p>15 Q. All right. It's on page 1 under</p> <p>16 "Results," last paragraph. They compare ULTRAPRO</p> <p>17 with Restorelle --</p> <p>18 A. Uh-huh.</p> <p>19 Q. -- and GYNEMESH PS. Do you see that?</p> <p>20 A. I do.</p> <p>21 Q. My question, Doctor, is what does the</p> <p>22 PS in GYNEMESH stand for?</p> <p>23 A. I -- I just don't remember.</p> <p>24 Q. Did you make any effort to find out?</p>	<p>1 Do you know if the mesh made in GYNEMESH PS is 100</p> <p>2 percent PROLENE?</p> <p>3 A. I mean, I believe it is. They -- they</p> <p>4 say the -- we sought to determine the predominant</p> <p>5 cell type within the area of implantation of the</p> <p>6 prototypical polypropylene mesh, GYNEMESH PS.</p> <p>7 Q. ULTRAPRO has an absorbable component,</p> <p>8 doesn't it?</p> <p>9 A. It's my understanding there's a</p> <p>10 resorbable polyester component. Wait a minute.</p> <p>11 Let me look at my report again. I can't. . .</p> <p>12 Yeah, so the PROLIFT, I know, has</p> <p>13 the -- the resorbable component. But she says</p> <p>14 these are polypropylene meshes in the objective.</p> <p>15 So that's what I read it, is that these are</p> <p>16 polypropylene meshes with different densities.</p> <p>17 That was what I understood to be the -- the purpose</p> <p>18 of this study.</p> <p>19 Q. Doctor -- Doctor, do you know the</p> <p>20 weight of the adsorbable component in ULTRAPRO?</p> <p>21 MR. BOWMAN: Object to form.</p> <p>22 THE WITNESS: I -- I don't remember</p> <p>23 right now.</p> <p>24 BY MR. HUTCHINSON:</p>
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<p>1 MR. BOWMAN: Object to form.</p> <p>2 THE WITNESS: I don't remember. I was</p> <p>3 looking at the density in the table. I don't know</p> <p>4 the specific formulation of that --</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Do you know how GYNEMESH PS may be</p> <p>7 different than GYNEMESH?</p> <p>8 A. I -- I -- I -- I don't remember how</p> <p>9 it's different from GYNEMESH.</p> <p>10 Q. Do you have any idea, as we sit here</p> <p>11 today, what the PS stands for?</p> <p>12 MR. BOWMAN: Object to form. Asked and</p> <p>13 answered.</p> <p>14 THE WITNESS: I mean, it's a company</p> <p>15 acronym. I don't -- I don't know why they call it</p> <p>16 a GYNEMESH PS. I don't remember.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Do you know if it's 100 percent</p> <p>19 PROLENE?</p> <p>20 A. I'd have to look at this again. I</p> <p>21 can't remember. One of these was -- maybe it was</p> <p>22 the Restorelle that had a -- had a resorbable</p> <p>23 component I thought.</p> <p>24 Q. Right. Let's talk about GYNEMESH PS.</p>	<p>1 Q. Let's talk about the -- the products</p> <p>2 that you're designated for. I will represent to</p> <p>3 you, Dr. Guelcher, and also represent to the Court</p> <p>4 that you've been designated for -- to give opinions</p> <p>5 for TVT, TVT-O, TVT ABBREVO, TVT-SECUR, TVT EXACT,</p> <p>6 PROSIMA, GYNEMESH PS, PROLIFT, and PROLIFT+M. Have</p> <p>7 you heard of all those products?</p> <p>8 A. I have.</p> <p>9 Q. Okay.</p> <p>10 THE WITNESS: Can we take a break for a</p> <p>11 few minutes? My stomach's a little bit -- is that</p> <p>12 okay?</p> <p>13 MR. HUTCHINSON: Yes, sir.</p> <p>14 THE WITNESS: Thank you.</p> <p>15 (Brief recess.)</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Dr. Guelcher, are you okay?</p> <p>18 A. Yeah. I'm okay.</p> <p>19 Q. All right. If you need to take another</p> <p>20 break, let me know. Okay?</p> <p>21 A. Okay. Thanks.</p> <p>22 Q. Doctor, do you know the weight of</p> <p>23 TVT-O?</p> <p>24 A. The weight? The density?</p>

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<p>1 Q. In grams -- yes. In grams per meter</p> <p>2 squared.</p> <p>3 A. I believe it's similar to the TVT,</p> <p>4 which is around 100.</p> <p>5 Q. What about TVT ABBREVO?</p> <p>6 A. I think it's similar. I think it's</p> <p>7 made from the same mesh.</p> <p>8 Q. Do you -- but do you know the weight,</p> <p>9 sir?</p> <p>10 A. 100.</p> <p>11 Q. Do you know the weight of TVT-SECUR?</p> <p>12 A. Let me look back at my report.</p> <p>13 Again -- well. . . (Reviews document.)</p> <p>14 Yeah. So it's in my report. The --</p> <p>15 the -- those SUI devices, the slings, the TVT-S,</p> <p>16 TVT ABBREVO, TVT-O, TVT are made from this</p> <p>17 105-gram-per-square-meter mesh. So they're all</p> <p>18 made from the same mesh, in my understanding.</p> <p>19 Q. And -- and, Doctor, is it your</p> <p>20 testimony for all TVT products the weight of the</p> <p>21 mesh per meter squared is the same?</p> <p>22 A. That's my understanding --</p> <p>23 Q. All right. Doctor --</p> <p>24 A. -- for the slings.</p>	<p>1 Q. The weight of the mesh and clinical</p> <p>2 problems; is that correct?</p> <p>3 A. Well, this wasn't really addressing</p> <p>4 that question. The -- the relationship was between</p> <p>5 the density of the mesh and the nature of the</p> <p>6 inflammatory infiltrate. That was the question she</p> <p>7 was looking at. It wasn't related. This was a</p> <p>8 preclinical study, I believe. So it wasn't -- this</p> <p>9 was in Rhesus macaque. So it wasn't --</p> <p>10 (Reporter interruption for</p> <p>11 clarification.)</p> <p>12 THE WITNESS: Rhesus macaque, which is</p> <p>13 the -- it's a -- it's a primate. So it's not a</p> <p>14 clinical study.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. There were a number of limitations in</p> <p>17 that study, weren't there?</p> <p>18 A. So she has a paragraph in the</p> <p>19 discussion about limitations of the study, which is</p> <p>20 typical in scientific research. That's what we do.</p> <p>21 Q. Okay. And, Doctor, if we look back at</p> <p>22 your expert report --</p> <p>23 A. Okay.</p> <p>24 Q. -- under "Summary of Opinions" --</p>
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<p>1 Q. And, Doctor, for the POP products, do</p> <p>2 you know the weight of the mesh per meter squared?</p> <p>3 A. I don't remember them all. The</p> <p>4 GYNEMESH is 45 grams per square meter. The -- the</p> <p>5 PROLIFT+M, that's the one that's the blend, has the</p> <p>6 resorbable polyester. After the polyester resorbs,</p> <p>7 the density is 28. So it's probably, roughly, you</p> <p>8 know, half, something in that range. So as the</p> <p>9 polyester resorbs, the density goes down.</p> <p>10 Q. And, Doctor, if we look at the Moalli</p> <p>11 paper --</p> <p>12 A. Okay.</p> <p>13 Q. -- that you have, the mesh didn't</p> <p>14 oxidize after 12 weeks, did it?</p> <p>15 A. Well, she wasn't testing for oxidation.</p> <p>16 She was looking at the cellular response. So I</p> <p>17 wouldn't say that it didn't oxidize. I just -- I</p> <p>18 don't think she reported that it did. But I don't</p> <p>19 know that she really did any testing for that.</p> <p>20 Q. A causal relationship wasn't</p> <p>21 established in that paper, was it, sir?</p> <p>22 A. A causal relationship --</p> <p>23 Q. Correct --</p> <p>24 A. -- between what?</p>	<p>1 A. Okay.</p> <p>2 Q. -- Number 1 --</p> <p>3 A. So we -- okay. Go ahead. Sorry.</p> <p>4 Q. Number 1 discusses "polypropylene</p> <p>5 reacts with molecular oxygen by autoxidation</p> <p>6 outside the body at elevated temperatures,</p> <p>7 resulting in chain scission and deterioration. . ."</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. At what elevated temperatures outside</p> <p>11 the body?</p> <p>12 A. I have to look at the details again.</p> <p>13 Temperatures above 100 C. That is 100 Celsius.</p> <p>14 Q. And -- and what is the normal body</p> <p>15 temperature in Celsius degrees of the human body?</p> <p>16 A. 37.</p> <p>17 Q. And what is autoxidation, Doctor?</p> <p>18 A. Well, "autoxidation" is a term that</p> <p>19 some use to describe the reactive -- the reaction</p> <p>20 of the polypropylene with molecular oxygen at</p> <p>21 elevated temperatures.</p> <p>22 Q. And we don't have elevated temperatures</p> <p>23 in the body, in vivo, do we, to the point where it</p> <p>24 would autoxidate?</p>

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<p>1 MR. BOWMAN: Object to the form.</p> <p>2 THE WITNESS: Well, the body</p> <p>3 temperature is 37 degrees C. So that reaction with</p> <p>4 molecular oxygen would be slow. I mean. . .</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. In fact, have you quantified how slow</p> <p>7 it would be?</p> <p>8 A. Well, I mean, Leibert addressed that</p> <p>9 question with molecular oxygen.</p> <p>10 Q. But my question to you, sir, is have</p> <p>11 you personally quantified that?</p> <p>12 A. No. Because I don't think it's</p> <p>13 relevant because there's more reactive forms of</p> <p>14 oxygen in the body that are causing the reaction.</p> <p>15 So. . .</p> <p>16 Q. What is -- what is required for PROLENE</p> <p>17 to undergo autoxidation?</p> <p>18 A. Well, PROLENE will undergo oxidation</p> <p>19 with molecular oxygen. It -- it -- it can happen</p> <p>20 at lower temperatures. It's just very, very slow.</p> <p>21 Q. Okay.</p> <p>22 A. So, I mean, it happens faster. Like</p> <p>23 any chemical reaction --</p> <p>24 Q. I understand.</p>	<p>1 increases with temperature.</p> <p>2 Q. Okay.</p> <p>3 A. As the temperature gets higher, it gets</p> <p>4 faster.</p> <p>5 Q. Can you -- can you tell me a</p> <p>6 temperature for PROLENE to undergo autoxidation?</p> <p>7 Can you tell me a specific temperature?</p> <p>8 MR. BOWMAN: Object to form.</p> <p>9 THE WITNESS: Well, I'm trying to</p> <p>10 answer. I -- I mean, it -- it's a chemical</p> <p>11 reaction. And the Arrhenius equation tells us that</p> <p>12 these reactions get faster as the temperature goes</p> <p>13 up. So the reaction can occur at physiological</p> <p>14 temperatures. It's just very slow.</p> <p>15 People do the studies at higher</p> <p>16 temperatures because they want to do them quickly.</p> <p>17 So if you increase the temperature to 100 degrees</p> <p>18 or 200 degrees Celsius, the reaction is faster.</p> <p>19 And that's why a lot of these older studies did it</p> <p>20 at higher temperatures.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. Right. But my question is what</p> <p>23 temperature is required for PROLENE to undergo</p> <p>24 autoxidation?</p>
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<p>1 A. -- it's -- it's faster at higher</p> <p>2 temperatures.</p> <p>3 Q. But what is required for PROLENE to</p> <p>4 undergo autoxidation in the body?</p> <p>5 A. In the body? You're asking a different</p> <p>6 question. I'm confused.</p> <p>7 Q. I am.</p> <p>8 A. Okay.</p> <p>9 Q. In general, what is -- strike that.</p> <p>10 A. Okay.</p> <p>11 Q. In general, what is required for</p> <p>12 PROLENE to undergo autoxidation?</p> <p>13 A. A -- I thought I answered it. It's --</p> <p>14 again, it would be the reaction with molecular</p> <p>15 oxygen is happening at faster rates at higher</p> <p>16 temperatures.</p> <p>17 Q. Okay.</p> <p>18 A. In -- in -- under body conditions, that</p> <p>19 reaction with molecular oxygen would be slow.</p> <p>20 Q. And --</p> <p>21 A. That's what I said.</p> <p>22 Q. And at what temperature, Doctor,</p> <p>23 would --</p> <p>24 A. Well, I mean, at what temperature -- it</p>	<p>1 A. I'm really trying to answer it. I</p> <p>2 mean, it's a chemical reaction. It -- it -- it --</p> <p>3 PROLENE is polypropylene with antioxidants. And</p> <p>4 the antioxidants can delay the reaction, but,</p> <p>5 eventually, it's going to happen. So. . .</p> <p>6 Q. At what rate -- excuse me.</p> <p>7 A. Go ahead. I -- I'm finished.</p> <p>8 Q. At what rate does PROLENE undergo</p> <p>9 autoxidation in the body?</p> <p>10 A. I don't know the rate. I've not</p> <p>11 measured it. But I wasn't really -- no. I don't</p> <p>12 know the rate that -- that thermal oxidation is</p> <p>13 going to. . .</p> <p>14 Q. If we -- if we look at the summary of</p> <p>15 opinions, Number 3 --</p> <p>16 A. Okay.</p> <p>17 Q. -- you discuss the dynamic environment</p> <p>18 where polypropylene mesh is implanted. Do you see</p> <p>19 that opinion?</p> <p>20 A. Yes.</p> <p>21 Q. What scientific evidence do you have,</p> <p>22 Dr. Guelcher, for chain scission having occurred</p> <p>23 with PROLENE in vivo?</p> <p>24 MR. BOWMAN: Object to form.</p>

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<p>1 THE WITNESS: Well, I mean, the paper</p> <p>2 published in 2015 by Mays, et al., showed</p> <p>3 reductions in molecular weight. Now, that wasn't</p> <p>4 PROLENE, but it was still polypropylene with</p> <p>5 antioxidants.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Okay.</p> <p>8 A. It's very similar material.</p> <p>9 Q. Okay. Let's -- let's focus on PROLENE,</p> <p>10 though, Doctor.</p> <p>11 What scientific evidence do you have</p> <p>12 for chain scission having occurred with PROLENE in</p> <p>13 vivo?</p> <p>14 MR. BOWMAN: Object to form.</p> <p>15 THE WITNESS: PROLENE in vivo. I don't</p> <p>16 know of a study that specifically looked at chain</p> <p>17 scission of PROLENE in vivo.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. And, Doctor, what scientific evidence</p> <p>20 do you have for any PROLENE implant having oxidized</p> <p>21 to produce a carbonyl group, a C double bond O?</p> <p>22 A. Can we go back to the chain scission</p> <p>23 one? I just remembered something or -- or I need</p> <p>24 to answer this first.</p>	<p>1 cracking, and molecular weight degradation.</p> <p>2 Q. Outside of Ethicon's internal</p> <p>3 studies --</p> <p>4 A. Okay.</p> <p>5 Q. -- are you aware of any scientific</p> <p>6 evidence that a PROLENE implant has oxidized to</p> <p>7 produce a carbonyl group?</p> <p>8 MR. BOWMAN: Object to form.</p> <p>9 THE WITNESS: So Clavé addressed --</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Okay.</p> <p>12 A. No. Clavé didn't -- he didn't -- he</p> <p>13 just says that he tested these different explants.</p> <p>14 So he doesn't necessarily divide it out by</p> <p>15 manufacturer, so it's --</p> <p>16 Q. I understand.</p> <p>17 A. -- it's not totally clear, right?</p> <p>18 Q. Okay.</p> <p>19 A. But, I mean, he does say -- he does</p> <p>20 observe evidence -- I've talked about this</p> <p>21 before -- evidence in the FTIR spectrum that I</p> <p>22 believe is indicative of oxidation. I know it's --</p> <p>23 we talked about this before. I don't --</p> <p>24 Q. Are you basing this solely on Clavé?</p>
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<p>1 Q. Well, let's stick with this one.</p> <p>2 A. Okay. So can you say it again?</p> <p>3 Q. What scientific evidence do you have</p> <p>4 for any PROLENE implant having oxidized to produce</p> <p>5 a carbonyl group?</p> <p>6 A. Let me look at my report again. There</p> <p>7 was some studies done at Ethicon that reported</p> <p>8 oxidation. And I'm trying to remember the details</p> <p>9 of exactly what they reported. I -- I believe they</p> <p>10 saw in those -- in those -- let me read my report</p> <p>11 again because I'm -- I'm . . . (Reviews document.)</p> <p>12 So there were some studies by Dr. Moy</p> <p>13 that noted the presence of oxidation products by</p> <p>14 FTIR. I believe that was incubated in hydrogen</p> <p>15 peroxide. There were some human explants where</p> <p>16 they observed degradation. And this question of</p> <p>17 oxidation of the materials was referred to in those</p> <p>18 studies.</p> <p>19 Q. Okay.</p> <p>20 A. They found that the cracked PROLENE</p> <p>21 surface is a composite of oxidized polypropylene,</p> <p>22 an adsorbed protein. So there was some internal</p> <p>23 Ethicon studies that looked at these questions of</p> <p>24 antioxidant depletion, oxidation of the surface,</p>	<p>1 A. Clavé would be the one that -- I think</p> <p>2 Céline Mary discussed this as well.</p> <p>3 Q. Okay. And is that the only scientific</p> <p>4 evidence that you're relying on is Clavé and the</p> <p>5 internal Ethicon documents for a PROLENE implant</p> <p>6 having oxidized to produce a carbonyl group?</p> <p>7 MR. BOWMAN: Object to form.</p> <p>8 THE WITNESS: Those are the documents</p> <p>9 that come to mind that I've testified about before.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Okay. Doctor, do you have -- and let's</p> <p>12 talk about -- my question is very specific as it</p> <p>13 relates to the nine specific products that you're</p> <p>14 here to give testimony about.</p> <p>15 A. Okay.</p> <p>16 Q. TVT, TVT-O, TVT ABBREVO, TVT-SECUR, TVT</p> <p>17 EXACT, PROSIMA, GYNEMESH PS, PROLIFT, and</p> <p>18 PROLIFT+M. Okay?</p> <p>19 A. Yes.</p> <p>20 Q. So my question, when I talk about the</p> <p>21 nine products, that's what I'm talking about.</p> <p>22 A. I understand.</p> <p>23 Q. All right. Do you have any scientific</p> <p>24 evidence that any of those nine products were</p>

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<p>1 implanted and oxidized to produce a carbonyl group?</p> <p>2 A. Again, the only study that could have</p> <p>3 included those devices would be the Clavé study</p> <p>4 where he took the 100 explants. And also the study</p> <p>5 with Dr. Iakovlev, but that was looking more at --</p> <p>6 that was explanted mesh as well, that looked at the</p> <p>7 degradation layer. But not -- well, he did look at</p> <p>8 the question of oxidation indirectly with the</p> <p>9 myeloperoxidase staining that we saw.</p> <p>10 Q. Right. But not specifically for those</p> <p>11 nine products, correct?</p> <p>12 A. Those nine products were not</p> <p>13 specifically mentioned in the Iakovlev study that I</p> <p>14 remember.</p> <p>15 Q. Thank you.</p> <p>16 So the only -- the only paper that</p> <p>17 you're relying on as it relates to whether any of</p> <p>18 those nine products oxidized to produce a carbonyl</p> <p>19 group, after it was implanted in vivo, is the Clavé</p> <p>20 study; is that correct?</p> <p>21 MR. BOWMAN: Object to form.</p> <p>22 THE WITNESS: For those nine products,</p> <p>23 that would be the one that I would. . .</p> <p>24 BY MR. HUTCHINSON:</p>	<p>1 Iakovlev study, we -- there were a lot of explants,</p> <p>2 but they weren't specifically named. They were</p> <p>3 slings, POPs, maybe some hernia mesh, too. But</p> <p>4 they -- the products weren't specifically named.</p> <p>5 So I -- I -- I can't -- I mean, it was a number of</p> <p>6 devices, right?</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. Yeah.</p> <p>9 A. Not -- not -- those specific products</p> <p>10 were not named.</p> <p>11 Q. Right. So I'm not asking about whether</p> <p>12 or not Iakovlev named them. My question to you,</p> <p>13 sir, is do you have any scientific evidence that</p> <p>14 any of those nine products have become embrittled</p> <p>15 in vivo?</p> <p>16 MR. BOWMAN: Object to form.</p> <p>17 THE WITNESS: Again, not direct -- what</p> <p>18 did you say? Embrittled? I mean, there's no</p> <p>19 direct evidence that those specific products has</p> <p>20 been published.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. And nor do you have any scientific</p> <p>23 evidence that any of those nine products have</p> <p>24 become embrittled, do you?</p>
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<p>1 Q. That would be the one that you would</p> <p>2 what?</p> <p>3 A. I'm just thinking. I'm sorry. I'm</p> <p>4 just thinking. You're -- you're referring</p> <p>5 specifically to the question of the carbonyl bond</p> <p>6 and the oxidation, right?</p> <p>7 Q. (Indicating yes.)</p> <p>8 A. Yeah. That would be the one that would</p> <p>9 come to mind.</p> <p>10 Q. Okay.</p> <p>11 A. That's the one I would rely on.</p> <p>12 Q. Okay. And Clavé is the same one that</p> <p>13 you rely on that states that the FTIR could</p> <p>14 neither -- neither confirm nor rule out oxidation,</p> <p>15 correct?</p> <p>16 A. Clavé states that.</p> <p>17 Q. Yes.</p> <p>18 A. I don't necessarily agree with it. But</p> <p>19 that's what the paper says.</p> <p>20 Q. And, Doctor, going back to these nine</p> <p>21 products, do you have any evidence that any of</p> <p>22 these nine products became embrittled in vivo?</p> <p>23 MR. BOWMAN: Object to form.</p> <p>24 THE WITNESS: I mean, again, in the</p>	<p>1 MR. BOWMAN: Object to form.</p> <p>2 THE WITNESS: I guess I'm a little hung</p> <p>3 up on scientific evidence. I mean, you mean</p> <p>4 directly measured, right? Reported?</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. (Indicating yes.)</p> <p>7 A. I mean, I believe -- well, you know my</p> <p>8 opinions. But I --</p> <p>9 Q. Well, I'm trying to find out your</p> <p>10 opinions.</p> <p>11 A. Okay.</p> <p>12 Q. So my opinions are -- that's the goal</p> <p>13 of today.</p> <p>14 A. No. I understand. But -- okay. So</p> <p>15 I'll state it again. I mean, I believe -- I don't</p> <p>16 want to argue about it. I mean, I believe that</p> <p>17 those devices are made of polypropylene, which</p> <p>18 these fundamental chemical reactions apply to.</p> <p>19 Now, has anyone specifically measured it for those</p> <p>20 devices? I -- I -- I don't know that that's been</p> <p>21 reported, but I believe the body of scientific</p> <p>22 evidence says that that's what's happening. That's</p> <p>23 my opinion. Okay?</p> <p>24 Q. But my question to you, do you know of</p>

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<p>1 any scientific evidence, as we sit here today, that</p> <p>2 any of those nine products have become embrittled</p> <p>3 in vivo?</p> <p>4 A. Again, I'm hung up on the scientific</p> <p>5 evidence. I mean, I -- I believe there's</p> <p>6 evidence --</p> <p>7 MR. BOWMAN: Object to the form.</p> <p>8 THE WITNESS: Okay.</p> <p>9 I don't know how to answer that. I</p> <p>10 mean, I --</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. Have you ever used the word "scientific</p> <p>13 evidence" as a polymer scientist?</p> <p>14 A. Well, I mean, it's a word. I mean, I</p> <p>15 know this word. But it can mean lots of things to</p> <p>16 lots of people, right?</p> <p>17 Q. Okay.</p> <p>18 A. Like anything.</p> <p>19 Q. So my --</p> <p>20 A. So I -- I'm just -- I'm just saying</p> <p>21 like a direct measurement of that phenomenon,</p> <p>22 I've -- I've not seen published.</p> <p>23 Q. Okay. You've not seen published it.</p> <p>24 A. Yeah.</p>	<p>1 evidence that any of those nine specific products</p> <p>2 have lost molecular weight in vivo?</p> <p>3 A. Again, no direct measurements of that.</p> <p>4 Q. And, Doctor, are you aware -- other</p> <p>5 than Clavé, are you aware of any literature that</p> <p>6 shows PROLENE produced a carbonyl group after it</p> <p>7 was implanted?</p> <p>8 A. Let me look at my report again. I know</p> <p>9 Mary was looking at -- Céline Mary did the PROLENE</p> <p>10 implant study with Guidoin.</p> <p>11 (Reporter interruption for</p> <p>12 clarification.)</p> <p>13 THE WITNESS: Guidoin, G-u-i-d-o-i-n.</p> <p>14 I just need to review what I wrote about that.</p> <p>15 (Reviews document.)</p> <p>16 Could you repeat the question? I'm --</p> <p>17 I'm sorry. I'm -- I'm not feeling well. I forgot</p> <p>18 it. I -- could you repeat the question, please?</p> <p>19 Oh, you're going to read it? Okay.</p> <p>20 That's fine.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. I can remember it. Other than Clavé,</p> <p>23 are you aware of any literature that shows PROLENE</p> <p>24 produced a carbonyl group after it was implanted?</p>
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<p>1 Q. Nor are you aware of any evidence that</p> <p>2 any of those nine products, specific products, have</p> <p>3 become embrittled in vivo, are you?</p> <p>4 MR. BOWMAN: Object to form.</p> <p>5 THE WITNESS: Again, I've not seen</p> <p>6 anybody actually measure that, I mean, if that's</p> <p>7 what you're. . .</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. And you haven't measured that, have</p> <p>10 you?</p> <p>11 A. No.</p> <p>12 Q. And, Doctor, are you aware of any</p> <p>13 scientific evidence that any of those nine products</p> <p>14 have lost molecular weight in vivo?</p> <p>15 MR. BOWMAN: Object to form.</p> <p>16 THE WITNESS: For those nine specific</p> <p>17 products, no one has shown -- published that they</p> <p>18 lose molecular weight.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. And are you aware, personally, of any</p> <p>21 evidence that any of those nine specific products</p> <p>22 have lost molecular weight in vivo?</p> <p>23 A. Could you rephrase that? I didn't --</p> <p>24 Q. Are you personally aware of any</p>	<p>1 A. Okay. I just need to find where I</p> <p>2 wrote about Céline Mary to answer that question.</p> <p>3 (Reviews document.)</p> <p>4 Q. But you would -- but other than Céline</p> <p>5 Mary, are you aware of any literature?</p> <p>6 A. Carbonyl and PROLENE due to oxidation.</p> <p>7 Q. After it was implanted.</p> <p>8 A. After it was implanted --</p> <p>9 Q. Yes, sir.</p> <p>10 A. -- in PROLENE. (Reviews document.) I</p> <p>11 can't think of anything other than those two</p> <p>12 studies.</p> <p>13 Q. Doctor, have you ever examined an</p> <p>14 explant of PROLENE from a patient?</p> <p>15 A. With Dr. Dunn, yes. And Dr. Iakovlev.</p> <p>16 Q. Was it -- what type of PROLENE explant</p> <p>17 was it?</p> <p>18 A. Oh, PROLENE.</p> <p>19 Q. Oh, I'm sorry. Maybe you might --</p> <p>20 might not have understood my question.</p> <p>21 A. I -- I --</p> <p>22 Q. Let's make sure the record's clear.</p> <p>23 A. I miss -- yeah.</p> <p>24 Q. That's fine. Don't worry about it.</p>

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<p>1 Have you ever examined a PROLENE</p> <p>2 explant from a patient?</p> <p>3 A. Not specifically PROLENE.</p> <p>4 Q. Sitting here today, do you have any</p> <p>5 evidence that a PROLENE explant has failed in the</p> <p>6 patient?</p> <p>7 MR. BOWMAN: Object to the form.</p> <p>8 THE WITNESS: Wow. Failed. What do</p> <p>9 you mean by "failed"? That's a -- could mean a lot</p> <p>10 of things. So what do you mean -- can you be more</p> <p>11 specific about failed?</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. It didn't do what it was intended to</p> <p>14 do.</p> <p>15 MR. BOWMAN: Object to form.</p> <p>16 THE WITNESS: Are you talking about</p> <p>17 mesh or sutures? I'm -- I -- it just seems like a</p> <p>18 broad question.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. Right.</p> <p>21 A. If you could --</p> <p>22 Q. You're here about -- you're here about</p> <p>23 nine mesh products, correct?</p> <p>24 A. Yes.</p>	<p>1 on in the report, right? It was more what happens</p> <p>2 to polypropylene. So there are studies that -- you</p> <p>3 know, I mean, the Clavé study is these meshes --</p> <p>4 you know, they were explanted because they failed</p> <p>5 so. . .</p> <p>6 Q. Can you tell us the name of a patient</p> <p>7 whose product did not work as intended?</p> <p>8 A. I mean, I didn't even -- I didn't look</p> <p>9 at patient records. I'm not a medical doctor.</p> <p>10 My -- my -- my report was focused on what happens</p> <p>11 to polypropylene that's implanted in the body and</p> <p>12 if there are --</p> <p>13 Q. And you can't tell us the name of</p> <p>14 somebody whose product has failed once it's in the</p> <p>15 body, correct?</p> <p>16 A. Well, I mean, I know that there's a --</p> <p>17 you know, the Huskey case, the Edwards case. I</p> <p>18 mean, these patients had complications associated</p> <p>19 with the mesh. So those are -- those are the cases</p> <p>20 that I have worked on.</p> <p>21 Q. Doctor, let's talk about</p> <p>22 biocompatibility.</p> <p>23 A. Okay.</p> <p>24 Q. You'll agree that Ethicon performed</p>
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<p>1 Q. All right.</p> <p>2 A. Because you keep saying PROLENE and</p> <p>3 mesh. I'm just getting confused.</p> <p>4 Q. All right. Have you ever examined --</p> <p>5 strike that.</p> <p>6 Do you have any scientific evidence</p> <p>7 that any of the nine products that you're giving</p> <p>8 testimony about today have failed in vivo?</p> <p>9 MR. BOWMAN: Object to form.</p> <p>10 THE WITNESS: I mean, that's why</p> <p>11 there's a lawsuit because there's an injury because</p> <p>12 of the device. So, I mean, I'm not focusing on the</p> <p>13 clinical aspects of that. I -- I guess I really</p> <p>14 don't understand what you're asking me.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. Are you aware of any evidence that a</p> <p>17 patient's mesh, from any of the nine products --</p> <p>18 A. Yeah.</p> <p>19 Q. -- failed to do what it was intended to</p> <p>20 do?</p> <p>21 A. I mean, I know there are clinical</p> <p>22 studies that have looked at this, but I just -- I</p> <p>23 don't -- I mean, I have to look at -- I can't</p> <p>24 remember -- I mean this wasn't what I was focusing</p>	<p>1 biocompatibility testing for the PROLENE --</p> <p>2 A. If you could be a little more specific.</p> <p>3 You mean ISO 10993 testing?</p> <p>4 Q. (Indicating yes.)</p> <p>5 A. Yeah. This is standard for any -- any</p> <p>6 biomedical device.</p> <p>7 Q. Do you have any criticisms of the</p> <p>8 biocompatibility testing that Ethicon did for any</p> <p>9 of the nine products?</p> <p>10 A. I've not testified about the ISO 10993</p> <p>11 biocompatibility testing, other than it's in my</p> <p>12 report that I -- I believe they should have done</p> <p>13 some of this testing with the oxidative medium, but</p> <p>14 that's -- that's not necessarily part of the -- I</p> <p>15 mean, there's -- there's a -- there are some tests</p> <p>16 on degradation with ISO 10993, but that medium is</p> <p>17 typically not used. My testimony has been that</p> <p>18 they should have looked at that.</p> <p>19 But I've not critiqued -- I've not</p> <p>20 expressed opinions about whether that -- could you</p> <p>21 repeat your question? I -- I'm sorry.</p> <p>22 Q. Well, do you have any criticisms --</p> <p>23 A. Criticism --</p> <p>24 Q. -- of Ethicon's biocompatibility</p>

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<p>1 testing of the PROLENE contained in any of the nine</p> <p>2 products, other than the oxidative opinions that</p> <p>3 you're --</p> <p>4 A. I've not discussed the ISO testing in</p> <p>5 my report. I've not opined on that.</p> <p>6 Q. But my question is, yes or no, do you</p> <p>7 have any opinions, other than the oxidative</p> <p>8 opinions that you're giving, regarding the</p> <p>9 biocompatibility testing of any of the nine</p> <p>10 products?</p> <p>11 A. No. It's not in my report. I've not</p> <p>12 discussed it.</p> <p>13 Q. You stated earlier that you have</p> <p>14 inspected mesh explants with Dr. Dunn.</p> <p>15 A. I've seen mesh -- mesh explants with</p> <p>16 Dr. Dunn and Dr. Iakovlev.</p> <p>17 Q. What products were those explants from?</p> <p>18 A. I believe it was an AMS mesh. I don't</p> <p>19 remember the -- it was -- I think it was POP, but I</p> <p>20 can't remember the exact device name.</p> <p>21 Q. AMS, American Medical Systems?</p> <p>22 A. That's right.</p> <p>23 Q. Have you ever inspected a PROLENE mesh</p> <p>24 explant from any of the nine products that we're</p>	<p>1 A. Seen these specific products?</p> <p>2 Q. Yes, sir.</p> <p>3 A. I've seen, I believe, the TVT, the</p> <p>4 TVT-O, the TVT-S, the ABBREVO because of previous</p> <p>5 litigation. The POP kits, I can't remember.</p> <p>6 Q. Have you ever seen TVT EXACT?</p> <p>7 A. I don't remember.</p> <p>8 Q. You don't remember if you've ever seen</p> <p>9 PROSIMA, GYNEMESH PS, PROLIFT or PROLIFT+M?</p> <p>10 A. Not those specific -- I mean, I've seen</p> <p>11 POP devices, but I -- I -- I can't remember, you</p> <p>12 know, who exactly they were manufactured by.</p> <p>13 Q. Have you ever held any of these</p> <p>14 products, these nine different products in your</p> <p>15 hand?</p> <p>16 A. Well, I mean, the -- the slings, the</p> <p>17 TVT, yeah. I've seen them and. . .</p> <p>18 Q. I'm sorry?</p> <p>19 A. Yeah, I mean, I've held them, stretched</p> <p>20 them, you know, these kinds of things.</p> <p>21 Q. Where?</p> <p>22 A. With Dr. Dunn at Vanderbilt. I mean,</p> <p>23 the testing that he did, right? So --</p> <p>24 Q. Does Dr. Dunn still has these exemplars</p>
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<p>1 here today about?</p> <p>2 MR. BOWMAN: Objection. Asked and</p> <p>3 answered.</p> <p>4 THE WITNESS: I've seen -- I -- in</p> <p>5 visiting Dr. Iakovlev with plaintiff's counsel a</p> <p>6 few years ago, I looked at a number of mesh. I</p> <p>7 don't remember him identifying any of those as</p> <p>8 PROLENE, but I've -- I've -- I've seen those</p> <p>9 explanted meshes.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. But you've never seen an explanted</p> <p>12 PROLENE mesh from any of the nine products,</p> <p>13 correct?</p> <p>14 A. Perhaps. I just -- I -- I don't know</p> <p>15 if it was PROLENE or not.</p> <p>16 Q. You can't tell us about it, sitting</p> <p>17 here today; is that right?</p> <p>18 A. No.</p> <p>19 Q. And you've never done any testing of a</p> <p>20 PROLENE mesh explant from any of the nine products,</p> <p>21 correct?</p> <p>22 A. Not from these nine products. Right.</p> <p>23 Q. Doctor, going to these nine products,</p> <p>24 have you ever seen these?</p>	<p>1 that you handled --</p> <p>2 A. I don't know. I'm sorry. I don't</p> <p>3 know. I don't know what he has right now.</p> <p>4 Q. But you've never retained a PROLENE</p> <p>5 exemplar, have you?</p> <p>6 A. I have not.</p> <p>7 Q. Do you know how long any of these nine</p> <p>8 products have been on the market?</p> <p>9 A. Well, the TVT has been out for a while,</p> <p>10 since the '90s. I -- I don't remember the exact</p> <p>11 dates they were introduced. But the TVT was the</p> <p>12 first.</p> <p>13 Q. Do you know the physical dimensions of</p> <p>14 any of these products?</p> <p>15 A. No. No, I don't.</p> <p>16 Q. Do you know how many newtons of force</p> <p>17 are placed on the mesh from any of these nine</p> <p>18 products once -- once they're implanted in vivo?</p> <p>19 MR. BOWMAN: Object to form.</p> <p>20 THE WITNESS: There are some studies</p> <p>21 that have looked at that. I don't -- I didn't</p> <p>22 really discuss that in this report. So I don't</p> <p>23 remember what those forces are. But there have</p> <p>24 been some studies that looked at the force on a</p>

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<p>1 sling. And I'm familiar with some of those</p> <p>2 studies.</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. Do you -- do you know -- well, do you</p> <p>5 have any opinions -- strike that.</p> <p>6 You're not an expert in the</p> <p>7 manufacturing process of PROLENE, pelvic mesh, are</p> <p>8 you?</p> <p>9 A. Manufacturing PROLENE? I'm -- I'm not</p> <p>10 expressing opinions about the specific</p> <p>11 manufacturing process.</p> <p>12 Q. Are these meshes -- are they woven or</p> <p>13 are they knitted for the nine different products?</p> <p>14 A. For the nine products?</p> <p>15 MR. BOWMAN: Object to form.</p> <p>16 THE WITNESS: Could you explain what</p> <p>17 you mean by woven versus knitted? That's kind of</p> <p>18 a --</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. Getting deep?</p> <p>21 A. I mean, what do you mean by "woven"? I</p> <p>22 mean, is it like --</p> <p>23 Q. Can you answer the question as it's</p> <p>24 phrased?</p>	<p>1 correct?</p> <p>2 A. Well, the -- yeah, the composition's</p> <p>3 different because it has these additives.</p> <p>4 MR. HUTCHINSON: I'm sorry. Did he say</p> <p>5 "well, yeah"?</p> <p>6 (Whereupon the previously mentioned</p> <p>7 answer was read back by the reporter.)</p> <p>8 THE WITNESS: I probably said -- yes,</p> <p>9 it's -- it has additives.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Doctor, turn to Exhibit 1. I'll</p> <p>12 represent to you and the Court that there are 44</p> <p>13 different plaintiffs named on the notice of</p> <p>14 deposition, starting with Marty Babcock --</p> <p>15 A. Okay.</p> <p>16 Q. -- and ending with Thelma Wright.</p> <p>17 That's 44 different cases.</p> <p>18 A. I see.</p> <p>19 Q. Did you know you were designated in 44</p> <p>20 cases in this litigation?</p> <p>21 A. I -- I didn't know the exact number of</p> <p>22 44. I knew it was a wave. So I knew there were a</p> <p>23 number of cases, but I wasn't familiar with the</p> <p>24 specific plaintiffs because I'm not giving</p>
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<p>1 MR. BOWMAN: Object to form.</p> <p>2 THE WITNESS: I'd have to refresh</p> <p>3 myself with the documents. I -- I -- I can't</p> <p>4 remember them.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. And as a material scientist, you'll</p> <p>7 agree that PROLENE has a different chemical</p> <p>8 composition than pure polypropylene, correct?</p> <p>9 A. So PROLENE has two antioxidants, one</p> <p>10 designed to prevent oxidation during</p> <p>11 high-temperature processing, another during</p> <p>12 storage. There are flow additives designed to make</p> <p>13 extrusion easier, calcium stearate, some</p> <p>14 surfactants. So there's other additives in there,</p> <p>15 but those additives are added mainly for</p> <p>16 manufacturing, in my understanding.</p> <p>17 Q. Right. But PROLENE has a chemical</p> <p>18 different composition -- strike that.</p> <p>19 PROLENE has a different chemical</p> <p>20 composition than pure PROLENE, correct?</p> <p>21 MR. BOWMAN: Object to form.</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. I'm sorry. PROLENE has a different</p> <p>24 chemical composition than pure polypropylene,</p>	<p>1 plaintiff-specific opinions.</p> <p>2 Q. Do you know what products any of these</p> <p>3 44 different women received?</p> <p>4 A. No. As I said, I didn't review the</p> <p>5 medical records. I'm -- I'm discussing -- my</p> <p>6 opinions are all related to PROLENE and</p> <p>7 polypropylene in -- in the body. Yes.</p> <p>8 Q. And you don't know any of the implant</p> <p>9 or explant dates for any of these women, correct?</p> <p>10 A. I don't. I haven't reviewed that.</p> <p>11 Q. And do you know the reason why any of</p> <p>12 these women had their mesh removed?</p> <p>13 A. Again, it's not -- I haven't reviewed</p> <p>14 their clinical records, medical records, so I</p> <p>15 wouldn't know.</p> <p>16 Q. Do you even -- do you even know if any</p> <p>17 of these women had their mesh removed?</p> <p>18 A. I know that some of them do because I</p> <p>19 know that some of these cases have specimens for</p> <p>20 pathology. I know Dr. Iakovlev and Dr. Timms have</p> <p>21 looked at that. So some of the patients have</p> <p>22 explants. Some don't.</p> <p>23 Q. Do you know who has an explant and who</p> <p>24 does not?</p>

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<p>1 A. No. Again, I didn't review the medical 2 records. 3 Q. Doctor, do you think it would have been 4 helpful for you to have reviewed or inspected a 5 plaintiff's explant in this litigation? 6 MR. BOWMAN: Object to form. 7 THE WITNESS: I mean, again, 8 Dr. Iakovlev is providing those patient-specific 9 opinions. My opinions are -- I mean, it would have 10 been helpful, but it's a lot of cases. It's a lot 11 of explants. It's a lot going on. 12 BY MR. HUTCHINSON: 13 Q. Right. But you wish you would have at 14 least had the opportunity to have reviewed an 15 implant -- I mean, I'm sorry -- an explant, 16 correct? 17 MR. BOWMAN: Object to form. 18 THE WITNESS: It would have been 19 helpful, but not realistic. I mean, it's just -- 20 BY MR. HUTCHINSON: 21 Q. Why wouldn't it have been realistic? 22 A. Well, there's -- there's just a lot of 23 plaintiffs. There's a lot of patients. There's a 24 lot of explants and there's other experts that are</p>	<p>1 when it was in her body? 2 MR. BOWMAN: Object to form. 3 THE WITNESS: I didn't specifically 4 look for oxidation in her mesh. What I've been 5 telling the jury is that my opinion is that 6 there's -- there's a significant risk of this 7 happening. It's a -- that's been the body of my 8 opinions and my testimony. But I'm not giving a 9 patient-specific opinion about Ms. Babcock. I -- I 10 didn't look at that. 11 BY MR. HUTCHINSON: 12 Q. Then, Doctor, are you -- did you 13 specifically look for oxidation for any of these 14 women listed on Exhibit 1, the notice of 15 deposition? 16 A. No. My understanding is that 17 Dr. Iakovlev is -- is doing that explant work. And 18 so this is -- this is an effort where there's lots 19 of experts involved. And Dr. Iakovlev is giving 20 those patient-specific opinions. 21 Q. Doctor, is it fair to say that you've 22 never done any analytical testing of explants of 23 PROLENE mesh? 24 A. I mean, I think you asked this before.</p>
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<p>1 working with those explants. So they have to be 2 managed in a -- in a way that's appropriate. And 3 if Dr. Iakovlev needs explants to do the microscopy 4 then -- for a patient-specific opinion, then he 5 needs to have priority to look at that explant. 6 Q. And, Doctor, have you ever asked to 7 inspect any of the explants available from these 8 women? 9 A. I've not asked in a specific case. 10 Q. Why not? 11 A. Again, there just isn't time. I mean, 12 it's -- it's not a realistic request. 13 Q. Doctor, if you were giving an opinion 14 about a specific product, would you not want to 15 have all the evidence available to you before 16 giving that opinion? 17 MR. BOWMAN: Object to form. 18 THE WITNESS: Again, I wasn't giving a 19 patient-specific opinion. I was giving an opinion 20 about what happens to polypropylene when it's 21 implanted in the body. That's -- so -- 22 BY MR. HUTCHINSON: 23 Q. I understand. But are you going to 24 tell the jury that Marty Babcock's mesh oxidized</p>	<p>1 Not PROLENE, but the AMS mesh. 2 Q. And you've never done any physical 3 property testing of PROLENE explants, have you? 4 A. Not for PROLENE. 5 Q. And not of pristine PROLENE, have you? 6 A. Well, again, the work that I referred 7 to earlier with Dr. Dunn, I believe there were some 8 Ethicon meshes in those measurements of molecular 9 weight, but it's been a long time and we haven't 10 been relying on that. But -- but we did something 11 like that a couple years ago. 12 Q. Doctor, you've never done any tests to 13 confirm oxidation of the mesh contained in any of 14 these women listed on the notice of deposition, 15 correct? 16 A. Again, I -- I thought I answered that, 17 too. Dr. Iakovlev is doing that. I'm not giving 18 those patient-specific opinions. 19 Q. And, Doctor, can you make any 20 prediction about when the mesh, from any of these 21 44 women, would oxidate in vivo? 22 MR. BOWMAN: Object to form. 23 THE WITNESS: Again, I -- my testimony 24 has been that it's -- it's a risk. There's a lot</p>

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<p>1 of factors that affect it and in what patient and</p> <p>2 at what time. It's not -- that's the problem is</p> <p>3 you -- you -- you can't predict it. I mean,</p> <p>4 that's -- that's the problem is it's unpredictable.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. In fact, you can't make any type of</p> <p>7 prediction of when Marty Babcock's mesh oxidized in</p> <p>8 her body, can you?</p> <p>9 MR. BOWMAN: Object to form.</p> <p>10 THE WITNESS: That's not in my opinions</p> <p>11 in my report. My report is that this is a risk.</p> <p>12 This -- this happens. And it depends on, you know,</p> <p>13 it's -- it's a risk. You can't predict when it's</p> <p>14 going to happen. You can't design around it.</p> <p>15 That's my opinion. It's not -- I didn't write an</p> <p>16 opinion specific to Ms. Babcock when it's going to</p> <p>17 oxidize or did it. I. . .</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. And you can't even sit here today</p> <p>20 telling us whether or not Marty Babcock's mesh</p> <p>21 oxidized in the body, can you?</p> <p>22 MR. BOWMAN: Object to form.</p> <p>23 THE WITNESS: I believe it's oxidizing.</p> <p>24 That's the chemical reaction. But the implications</p>	<p>1 tells you that that would be -- you would expect it</p> <p>2 to oxidize and degrade. The -- the timing of that</p> <p>3 is unpredictable. That's what I've said. I didn't</p> <p>4 measure it. But scientific evidence --</p> <p>5 polypropylene oxidizes. There are cells in the</p> <p>6 body that make reactive oxygen species, and you</p> <p>7 would expect it to oxidize in the body based on</p> <p>8 the -- what we know scientifically.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. I understand that. But I'm -- my</p> <p>11 question is related to these 44 women. Can you</p> <p>12 tell us, to a reasonable degree of scientific</p> <p>13 certainty, whether or not the mesh, in any of these</p> <p>14 44 women, ever oxidized?</p> <p>15 MR. BOWMAN: Object to form. This is</p> <p>16 asked and answered.</p> <p>17 THE WITNESS: I feel like we're going</p> <p>18 to go round and round on this.</p> <p>19 (Simultaneous speaking.)</p> <p>20 MR. BOWMAN: I'm going to instruct him</p> <p>21 not to answer.</p> <p>22 (Reporter interruption for</p> <p>23 clarification.)</p> <p>24 MR. BOWMAN: I said if we're going to</p>
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<p>1 of that are difficult to predict.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. But my question is, sir, are you</p> <p>4 testifying, to a reasonable degree of scientific</p> <p>5 certainty, without having reviewed an explant, that</p> <p>6 Marty Babcock's mesh is oxidizing in her body?</p> <p>7 MR. BOWMAN: Object to form.</p> <p>8 THE WITNESS: I mean, I believe that</p> <p>9 the science tells you it's oxidizing. I did not</p> <p>10 specifically measure it.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. Thank you. In fact, you didn't</p> <p>13 specifically measure oxidation of any of the women</p> <p>14 listed in Exhibit Number 1, correct?</p> <p>15 A. I've already answered that. No.</p> <p>16 Q. Okay.</p> <p>17 A. Yeah, I didn't do that.</p> <p>18 Q. And you can't tell us whether or not</p> <p>19 the mesh of any of the women listed in Exhibit 1</p> <p>20 oxidized in their body, can you?</p> <p>21 MR. BOWMAN: Object to the form. Asked</p> <p>22 and answered.</p> <p>23 THE WITNESS: I believe I've asked --</p> <p>24 I've answered this. I mean, it's -- the science</p>	<p>1 keep asking the same question, I'm going to start</p> <p>2 instructing him not to answer.</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. I need a clean answer, then I'll move</p> <p>5 on.</p> <p>6 MR. BOWMAN: Objection.</p> <p>7 THE WITNESS: I'm giving you my clean</p> <p>8 answer. I've said this in trials. I've said this</p> <p>9 in depositions. You know the record of my</p> <p>10 testimony. It hasn't changed.</p> <p>11 The scientific principles states that</p> <p>12 this chemical reaction is going to occur. It's</p> <p>13 going to oxidize. The clinical implications of</p> <p>14 that are unknown. I did not specifically look at</p> <p>15 oxidation in these meshes. My testimony has been</p> <p>16 that these reactions are occurring. And the</p> <p>17 clinical implication of that in a specific patient</p> <p>18 is unknown. It's unpredictable. That's been my</p> <p>19 testimony. I --</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. And you can't tell us when it's</p> <p>22 occurring, can you, in any of these 44 women?</p> <p>23 A. I think that's what unpredictable means</p> <p>24 is you don't -- you don't know when it's -- when it</p>

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<p>1 could happen, when it -- when it happens. You</p> <p>2 don't -- you don't know when that's going to occur.</p> <p>3 Q. Doctor, can you tell us the name of a</p> <p>4 patient who has had their mesh removed specifically</p> <p>5 because of oxidations?</p> <p>6 A. I mean, in the papers, the patient</p> <p>7 names aren't provided. It's a violation of</p> <p>8 confidentiality rules. I mean, in the --</p> <p>9 Q. Okay. Then let's not --</p> <p>10 A. In a specific case.</p> <p>11 Q. Okay. Then let's not look --</p> <p>12 A. I mean, all these case --</p> <p>13 Q. Let's look at the -- let's not look at</p> <p>14 the papers or the literature.</p> <p>15 A. I mean, I don't want to get into</p> <p>16 patient names. That's kind of -- there's all these</p> <p>17 cases, and this is a specific case. I mean, we've</p> <p>18 looked at the plaintiffs in this specific case. I</p> <p>19 don't -- I'm not comfortable discussing specific</p> <p>20 patients from other litigations.</p> <p>21 Q. I understand. And I'm not asking you</p> <p>22 to discuss any patients from any literature or any</p> <p>23 other litigation. What I'm asking about is the</p> <p>24 Ethicon litigation.</p>	<p>1 I said, I haven't reviewed their records. I don't</p> <p>2 know why their mesh was removed.</p> <p>3 Q. Okay. And you -- you don't -- you</p> <p>4 can't tell us the name of one patient, of any of</p> <p>5 these nine products, who had their mesh removed</p> <p>6 specifically because of oxidation?</p> <p>7 A. I just answered that.</p> <p>8 Q. No. You told me it was a strange</p> <p>9 question.</p> <p>10 A. Well, it is a strange question. I</p> <p>11 stick by that.</p> <p>12 But meshes are removed because of</p> <p>13 complications, like pain, erosion, and extrusion</p> <p>14 that a clinician can see. So -- I -- I just don't</p> <p>15 want to be trapped in some kind of answer, yes or</p> <p>16 no, to a question like that. They --</p> <p>17 Q. Well, Doctor, I'm entitled to flesh out</p> <p>18 your opinions. And my question is can you tell us,</p> <p>19 sitting here today, the name of a person, who</p> <p>20 received any one of these nine products, who had</p> <p>21 their mesh specifically removed because of</p> <p>22 oxidation?</p> <p>23 MR. BOWMAN: You can answer yes or no.</p> <p>24 THE WITNESS: No, none of these</p>
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<p>1 Can you tell us the name of a patient,</p> <p>2 who received any one of the nine products, who had</p> <p>3 their mesh specifically removed because of</p> <p>4 oxidation?</p> <p>5 A. Why would you remove a mesh for</p> <p>6 oxidation? You remove it for another complication.</p> <p>7 I mean, it's not -- oxidation leads to</p> <p>8 embrittlement and degradation. So -- I mean,</p> <p>9 they're -- they're removed because they become</p> <p>10 embrittled. They extrude. They cause pain. Not</p> <p>11 because -- I mean, there's not -- you wouldn't --</p> <p>12 I'm confused. I'm sorry. Go ahead.</p> <p>13 MR. HUTCHINSON: Move to strike as</p> <p>14 nonresponsive.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. Doctor, I'm asking for a name of</p> <p>17 somebody who received any one of these nine</p> <p>18 products who had their mesh specifically removed</p> <p>19 because of oxidation. Can you tell us a name? Yes</p> <p>20 or no? And then I'll move on.</p> <p>21 A. This is a strange question. You</p> <p>22 wouldn't remove a mesh for oxidation. It's a very</p> <p>23 early event. I mean, I don't know that any of</p> <p>24 these patients had it removed for oxidation. Like</p>	<p>1 patients --</p> <p>2 MR. BOWMAN: If you can.</p> <p>3 THE WITNESS: To my knowledge, none of</p> <p>4 them -- I don't -- I don't know that any of them --</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. I'm sorry. "To my knowledge none of</p> <p>7 them" what?</p> <p>8 A. I don't know -- I said I don't know why</p> <p>9 the mesh was removed in these patients. So I</p> <p>10 wouldn't know if it was removed to oxidation</p> <p>11 [verbatim]. I don't know that any of them had it</p> <p>12 removed for -- because of oxidation.</p> <p>13 Q. Okay.</p> <p>14 A. I don't know that.</p> <p>15 Q. And you can't tell us the name of one</p> <p>16 person who had their mesh removed because of</p> <p>17 oxidation, can you?</p> <p>18 A. Why are you --</p> <p>19 MR. BOWMAN: Object to form.</p> <p>20 THE WITNESS: I'm really -- I'm getting</p> <p>21 a little frustrated. Can we answer this and take a</p> <p>22 break? I don't want to get angry.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. That's fine. Just answer it, and then</p>

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<p>1 we can take a break.</p> <p>2 A. The name -- the 44 names on this</p> <p>3 list --</p> <p>4 Q. My question to you is can you tell us</p> <p>5 the name, sir, of one patient who received any one</p> <p>6 of the nine products who had their mesh</p> <p>7 specifically removed because of oxidation?</p> <p>8 A. I've already answered that. I don't</p> <p>9 know of a patient that had it removed because of</p> <p>10 oxidation of these 44 patients.</p> <p>11 Q. Okay. Or of any patients, not</p> <p>12 necessarily the 44.</p> <p>13 A. I'm going with these 44 patients</p> <p>14 because it's this litigation. I don't want to</p> <p>15 answer questions about other litigation.</p> <p>16 Q. Okay.</p> <p>17 A. I thought I made that clear. I'm</p> <p>18 talking about these 44 patients.</p> <p>19 Q. Okay. Thank you.</p> <p>20 A. Can we take a break? I don't want to</p> <p>21 get agitated.</p> <p>22 MR. HUTCHINSON: That's fine.</p> <p>23 (Brief recess.)</p> <p>24 BY MR. HUTCHINSON:</p>	<p>1 question.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. All right. Doctor, have you ever</p> <p>4 instructed your students at Vanderbilt to use</p> <p>5 scientific data in reaching a conclusion?</p> <p>6 MR. BOWMAN: Object to form.</p> <p>7 THE WITNESS: Again, we do experiments,</p> <p>8 make measurements and test hypotheses.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. All right. And, Doctor, let's talk</p> <p>11 about these nine specific products that you're here</p> <p>12 to give testimony about.</p> <p>13 Are you aware of any data that confirms</p> <p>14 these nine specific products degraded to the extent</p> <p>15 it compromised the functionality of the product?</p> <p>16 MR. BOWMAN: Object to form.</p> <p>17 THE WITNESS: Again, you've asked this</p> <p>18 many times. I've not looked at physical changes in</p> <p>19 these specific products, these patients. I've not</p> <p>20 looked at that. I didn't test the explants.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. I understand that. But my question is</p> <p>23 a little bit more general, is -- and it relates to</p> <p>24 these nine specific products, okay? Are you aware</p>
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<p>1 Q. Dr. Guelcher, do you have any evidence</p> <p>2 to confirm that any of the -- these women had</p> <p>3 molecular weight loss of their explants?</p> <p>4 A. You know, I didn't look at molecular</p> <p>5 weight in -- as I said before, I didn't look at</p> <p>6 their explants. I didn't look at their patient</p> <p>7 records.</p> <p>8 Q. Doctor, do you have any evidence to</p> <p>9 confirm that any of these women -- and, again, I'm</p> <p>10 talking about the women that you're here to give</p> <p>11 testimony about today -- had explants that had a</p> <p>12 change in physical properties?</p> <p>13 A. No. I didn't look at patient explants,</p> <p>14 so I don't know the change in physical properties.</p> <p>15 Q. And, Doctor, do you have any evidence</p> <p>16 to confirm that these women's explants lost any</p> <p>17 antioxidants?</p> <p>18 A. No. Again, that wasn't measured,</p> <p>19 whether they lost antioxidants.</p> <p>20 Q. And, Doctor, using solid scientific</p> <p>21 data is good science, isn't it?</p> <p>22 MR. BOWMAN: Object to form.</p> <p>23 THE WITNESS: That's a very vague --</p> <p>24 I'm not -- I'm not sure what you mean by that</p>	<p>1 of any data that confirms these nine products will</p> <p>2 degrade to the extent their intended function is</p> <p>3 compromised during a woman's lifetime?</p> <p>4 MR. BOWMAN: Object to the form.</p> <p>5 THE WITNESS: Again, you asked this</p> <p>6 before and I said, no, for these products that's</p> <p>7 not been directly measured.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. And, Doctor, do you know -- we talked</p> <p>10 about -- well, strike that.</p> <p>11 Do you know what the mechanism of</p> <p>12 action of tissue negatively reacting to any of</p> <p>13 these nine products is?</p> <p>14 MR. BOWMAN: Object to form.</p> <p>15 THE WITNESS: Can you repeat that?</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Right. Doctor, do you believe that the</p> <p>18 tissue in women negatively reacts to any of these</p> <p>19 nine products?</p> <p>20 A. The --</p> <p>21 Q. Or are you qualified to give that</p> <p>22 opinion?</p> <p>23 A. Well, I believe I'm -- that's what my</p> <p>24 report is about. That's what these papers are</p>

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<p>1 about, is that the -- the macrophage is to treat</p> <p>2 reactive oxygen that degrades the polypropylene.</p> <p>3 Has that been tested for these nine specific</p> <p>4 products? Well, you asked about this earlier. And</p> <p>5 I -- I said I don't know of any study looking at</p> <p>6 these nine specific projects, but that's --</p> <p>7 Q. You mean products, not projects?</p> <p>8 A. Products. But that's -- but the nature</p> <p>9 of the chemistry in the inflammatory reaction and</p> <p>10 the nature of the material tells us that these</p> <p>11 things will happen, but --</p> <p>12 Q. All right. Well, Doctor, what is --</p> <p>13 A. -- it's not been specifically measured,</p> <p>14 for these products.</p> <p>15 Q. What is the mechanism of action of how</p> <p>16 tissue negatively reacts to any of these nine</p> <p>17 products?</p> <p>18 MR. BOWMAN: Object to form.</p> <p>19 THE WITNESS: I mean -- but -- but</p> <p>20 my -- my struggle is your question is very vague.</p> <p>21 I mean, there's a number of tissue reactions.</p> <p>22 There can be a fibrotic response, which is</p> <p>23 fibroblasts migrating in and laying down a scar</p> <p>24 plate, by depositing extra cellular matrix</p>	<p>1 properties, again, is -- is broad. I mean, it's --</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Of the -- of the material.</p> <p>4 A. It --</p> <p>5 Q. Oxidation -- you talked about oxidation</p> <p>6 leads to reduced molecular weight. Oxidation also</p> <p>7 leads to reduced physical properties, correct?</p> <p>8 A. Like what physical properties are you</p> <p>9 referring to? I'd like you to be more specific. I</p> <p>10 mean, it's -- it's reducing the molecular weight,</p> <p>11 which leads to embrittlement. That's the science</p> <p>12 of polypropylene oxidation. It's in the report.</p> <p>13 I'm not sure what you mean by other</p> <p>14 physical properties. It would help me if you could</p> <p>15 be more specific.</p> <p>16 Q. Well, oxidation, Doctor, causes a</p> <p>17 reduction in tensile strength, doesn't it?</p> <p>18 A. Reduction -- that's a mechanical</p> <p>19 property, right? So. . .</p> <p>20 Q. Well, strike that.</p> <p>21 So let me be clear, and we can just</p> <p>22 move on.</p> <p>23 A. Okay. I'm just struggling to</p> <p>24 understand your question.</p>
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<p>1 resulting in a scar plate. I should be more</p> <p>2 precise.</p> <p>3 There's the macrophages and other</p> <p>4 inflammatory cells, foreign body giant cells, that</p> <p>5 migrate into the mesh, adhere to the mesh, secrete</p> <p>6 reactive oxygen species, including hydroxyl</p> <p>7 radicles, that oxidize the polypropylene. That --</p> <p>8 that -- that's in my report. That's the -- that's</p> <p>9 the tissue response. The primary components are</p> <p>10 the fibroblasts and -- and with the collagen matrix</p> <p>11 deposition and the -- and the macrophages.</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. Doctor, can you tell us from a</p> <p>14 physiological standpoint how oxidation causes pain</p> <p>15 in a woman?</p> <p>16 A. Again, it's in my report. Oxidation</p> <p>17 leads to reduction of molecular weight,</p> <p>18 embrittlement, and that can lead to cracking, which</p> <p>19 can lead to erosions and pain. It's hard plastic</p> <p>20 in the pelvic floor. That's going to cause pain.</p> <p>21 Q. And oxidation also leads to reduction</p> <p>22 in physical properties, correct?</p> <p>23 MR. BOWMAN: Objection to form.</p> <p>24 THE WITNESS: What -- physical</p>	<p>1 Q. That's fine. Oxidation -- stay with</p> <p>2 me. Do you need to take another break?</p> <p>3 A. No. I'm fine.</p> <p>4 Q. All right. Oxidation leads to a</p> <p>5 reduction in mechanical properties of the mesh,</p> <p>6 correct?</p> <p>7 A. Yeah. It leads to changes. It leads</p> <p>8 to embrittlement, which would be the material</p> <p>9 becomes brittle rather than a ductile polymer.</p> <p>10 Q. And a loss of molecular weight leads to</p> <p>11 reduced tensile strength, doesn't it?</p> <p>12 A. Yeah, I mean, it can. If you have a</p> <p>13 reduction in molecular weight, it -- it depends</p> <p>14 on -- reduction in molecular weight can lead to</p> <p>15 reduced strength.</p> <p>16 Q. Okay. And we're talking about strength</p> <p>17 is how -- is how tough a polymer is; is that right?</p> <p>18 A. Well, I wouldn't say -- tough is an</p> <p>19 area under the stress versus strain curve, but</p> <p>20 strength is the force or the -- you know, the --</p> <p>21 the stress, the force per unit area required to</p> <p>22 break the fiber or the mesh.</p> <p>23 Q. Well, loss of molecular weight leads to</p> <p>24 a decrease in toughness under the stress-strain</p>

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<p>1 curve, doesn't it?</p> <p>2 A. I mean, it can. It's -- it's -- if</p> <p>3 it's -- if it becomes embrittled, it's going to</p> <p>4 fail at a lower elongation or strain, and that</p> <p>5 would lead to reduction in toughness.</p> <p>6 Q. In fact, that's what you would expect</p> <p>7 as a polymer scientist. If a polymer becomes</p> <p>8 embrittled there will be a decrease in toughness</p> <p>9 under the stress-strain curve, correct?</p> <p>10 A. It -- generally speaking, it would, but</p> <p>11 the problem is this is happening at the surface of</p> <p>12 the fiber. So it's difficult to measure it. It's</p> <p>13 not uniformly distributed across the diameter of</p> <p>14 the fiber. So you may not be able to measure a</p> <p>15 difference in strength even if the fiber is</p> <p>16 cracked. It -- it just depends on other things.</p> <p>17 Because strength is a bulk volume average property</p> <p>18 versus what's happening at the surface.</p> <p>19 Q. Sir, would a crack in a polymer</p> <p>20 increase or decrease its mechanical properties?</p> <p>21 A. Depends on how deep it is. If it's --</p> <p>22 if it's -- if it's a penetrating -- you can have</p> <p>23 crack propagation which can lead to failure of the</p> <p>24 fiber.</p>	<p>1 A. Well, if the strain and stress to</p> <p>2 break -- if the tensile strength or the elongation</p> <p>3 at break --</p> <p>4 (Reporter interruption for</p> <p>5 clarification.)</p> <p>6 THE WITNESS: Elongation at break --</p> <p>7 sorry -- is reduced, then the toughness would be</p> <p>8 reduced if it's the area under the stress-strain</p> <p>9 curve.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. In fact, Doctor, you're familiar with</p> <p>12 the area under the stress-strain curve, aren't you?</p> <p>13 A. Familiar with it?</p> <p>14 Q. Yeah. You're familiar with the</p> <p>15 concept --</p> <p>16 A. Yes.</p> <p>17 Q. -- toughness as defined --</p> <p>18 A. Yeah, I've published on that. Yes.</p> <p>19 Q. Yes. Okay. And that's something you</p> <p>20 teach your students about; is that right?</p> <p>21 A. I've taught that before.</p> <p>22 Q. Doctor, when we get -- let's go -- go</p> <p>23 back to antioxidants for a minute. I think you and</p> <p>24 I can agree that the formulated product PROLENE has</p>
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<p>1 Q. Doctor, would you expect a crack in a</p> <p>2 polymer to ever increase the mechanical properties</p> <p>3 of that polymer?</p> <p>4 A. Seems unlikely.</p> <p>5 Q. Thank you.</p> <p>6 And, Doctor, if there was a crack in a</p> <p>7 PROLENE fiber, you would expect that PROLENE fiber</p> <p>8 to have reduced mechanical properties, wouldn't</p> <p>9 you, sir?</p> <p>10 A. As I said, it depends on the depths of</p> <p>11 the crack. It depends on -- I mean, the</p> <p>12 embrittlement -- these reactions all occur at the</p> <p>13 surface of the fiber, and they move inwards. So</p> <p>14 it -- it just depends. I mean, if the crack were</p> <p>15 deep enough, it would affect the mechanical</p> <p>16 properties. But it's not always going to be --</p> <p>17 it's difficult to say every single time. I mean,</p> <p>18 cracks generally reduce mechanical properties, but</p> <p>19 it -- it's going to depend on the depth of the</p> <p>20 crack and crack propagation and all that.</p> <p>21 Q. I understand. And -- and -- and,</p> <p>22 Doctor, you would expect a crack in a PROLENE fiber</p> <p>23 to decrease the toughness of that PROLENE fiber,</p> <p>24 wouldn't you?</p>	<p>1 antioxidants in it, correct?</p> <p>2 A. It does. DLTDP -- and I don't remember</p> <p>3 the name of the other one. There are two</p> <p>4 different -- one is a radical scavenger. The</p> <p>5 other, I think, is a sulfa compound, thio compound.</p> <p>6 I can't -- thioester. I can't remember the exact</p> <p>7 chemical formula.</p> <p>8 (Whereupon Exhibit 5 was marked as an</p> <p>9 exhibit.)</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Doctor, I'll hand you what we'll mark</p> <p>12 as Exhibit 5 to your deposition.</p> <p>13 A. Okay.</p> <p>14 Q. Can you draw out the chemical structure</p> <p>15 of DLTDP as used in PROLENE in any of these nine</p> <p>16 products?</p> <p>17 MR. BOWMAN: Object to form.</p> <p>18 THE WITNESS: I don't remember the</p> <p>19 chemical structure of the -- of the antioxidant.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Doctor, can you draw out the chemical</p> <p>22 structure of Sanotox R, on that sheet of paper I've</p> <p>23 handed you marked as Exhibit 5, as used in any of</p> <p>24 these nine products?</p>

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<p>1 A. I don't remember the chemical structure</p> <p>2 that I could write it down.</p> <p>3 Q. You could?</p> <p>4 A. No. I don't remember what it exactly</p> <p>5 is.</p> <p>6 Q. You can't draw the chemical structures</p> <p>7 on Exhibit 5 of DLTPD or Sanotox R, can you?</p> <p>8 MR. BOWMAN: Object to form.</p> <p>9 THE WITNESS: I mean, I haven't</p> <p>10 memorized their chemical structures. I know what</p> <p>11 they do and what they are, but I haven't memorized</p> <p>12 their chemical structures. I don't typically do</p> <p>13 that in my. . .</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Doctor, can you show me chemically how</p> <p>16 they perform in oxidation -- I'm sorry.</p> <p>17 Can you show me chemically how they</p> <p>18 perform as antioxidants, on that piece of paper as</p> <p>19 Exhibit 5?</p> <p>20 MR. BOWMAN: Object to form.</p> <p>21 THE WITNESS: Again, that's a complex</p> <p>22 reaction mechanism. I haven't memorized it. It's</p> <p>23 in a number of books. But my understanding is it's</p> <p>24 basically, you know, radical scavenger. I mean,</p>	<p>1 blend. It's a composite. It's polypropylene with</p> <p>2 these other additives in it. So I'm not -- you</p> <p>3 want me to draw the -- I mean, I'm not sure what</p> <p>4 you want me to do.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. I want you to draw the chemical</p> <p>7 structure for PROLENE. Can you do that on Exhibit</p> <p>8 5?</p> <p>9 MR. BOWMAN: Object to form.</p> <p>10 THE WITNESS: You can't draw the</p> <p>11 chemical structure of PROLENE because it's</p> <p>12 polypropylene with all these other -- other</p> <p>13 additives in it. So it's not a -- it's not a</p> <p>14 specific molecule. It's a formulation. It's a</p> <p>15 blend. It's not --</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Sir, do you know what the chemical</p> <p>18 structure for polypropylene looks like?</p> <p>19 A. Yeah. I mean, it's in my report. I</p> <p>20 mean, it's --</p> <p>21 Q. I mean, Doctor, where, on that chemical</p> <p>22 chain, are the additives of DLTPD and Sanotox R</p> <p>23 added? Can you tell us that?</p> <p>24 MR. BOWMAN: Object to form.</p>
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<p>1 scavenging free radicles that -- that are produced</p> <p>2 in this oxidation reaction. Whether they come</p> <p>3 from -- I'll leave it at that.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Doctor, on Exhibit 5, can you draw the</p> <p>6 chemical structure for PROLENE as used in any of</p> <p>7 these nine products?</p> <p>8 MR. BOWMAN: Object to form as to</p> <p>9 "draw."</p> <p>10 THE WITNESS: Again, it's a difficult</p> <p>11 question. I mean, PROLENE is polypropylene with</p> <p>12 some additives in it. So it's -- I don't remember</p> <p>13 the exact compositions of the additives. It's in</p> <p>14 the, you know, half percent to percent range. It's</p> <p>15 pretty low.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Right. And my question, Doctor, is not</p> <p>18 whether you remember, but can you draw the chemical</p> <p>19 structure for PROLENE as used in any of these nine</p> <p>20 products on the piece of paper I've marked as</p> <p>21 Exhibit 5 to your deposition?</p> <p>22 MR. BOWMAN: Object to form.</p> <p>23 THE WITNESS: But you can't draw the</p> <p>24 composition of PROLENE. It's a -- it's a -- it's a</p>	<p>1 THE WITNESS: I don't -- I don't think</p> <p>2 that they're added to the chain. They're blended</p> <p>3 in with the polymer. I don't -- I don't think</p> <p>4 they're necessarily reacting with it.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Doctor, do you know what step in the</p> <p>7 manufacturing process DLTPD or Sanotox R is added?</p> <p>8 A. In the manufacturing process of</p> <p>9 PROLENE?</p> <p>10 Q. Yes, sir.</p> <p>11 A. Could you repeat the question? I'm</p> <p>12 not, again, sure what you're asking.</p> <p>13 Q. Do you know what step in the</p> <p>14 manufacturing process where DLTPD and Sanotox R are</p> <p>15 added?</p> <p>16 MR. BOWMAN: Object to form.</p> <p>17 THE WITNESS: I mean, these are</p> <p>18 added -- it's in my report. They're -- they're</p> <p>19 added to protect PROLENE.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Right. We're going to get to the</p> <p>22 reason in a minute. But I'm asking you what step</p> <p>23 in the manufacturing process --</p> <p>24 A. Well, it's --</p>

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<p>1 Q. -- these additives are added to</p> <p>2 polypropylene?</p> <p>3 A. Well, I was getting there. But -- so</p> <p>4 the PROLENE is manufactured as pellets that are</p> <p>5 then extruded into a monofilament, and my</p> <p>6 understanding is it's added to those pellets prior</p> <p>7 to the extrusion step. That some of the flow</p> <p>8 additives can help with flow of the melt polymer</p> <p>9 during extrusion, and then the antioxidants, one of</p> <p>10 them at least, is protecting it from high</p> <p>11 temperature oxidation during extrusion. So that's</p> <p>12 my understanding of when those additives are added.</p> <p>13 Q. Doctor, have you ever done any type of</p> <p>14 analysis to determine whether or not the</p> <p>15 antioxidants, contained in any of these nine</p> <p>16 products, have been depleted?</p> <p>17 MR. BOWMAN: Object to form.</p> <p>18 THE WITNESS: I've not done that, but</p> <p>19 Ethicon had done that.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. And you had the equipment at your lab</p> <p>22 at Vanderbilt to do that testing, didn't you, sir?</p> <p>23 A. I could do that at Vanderbilt, but</p> <p>24 it -- it -- it takes funding to do that. I don't</p>	<p>1 sit here today -- or strike that.</p> <p>2 Do you have any scientific data that</p> <p>3 shows antioxidants from any of these nine products</p> <p>4 are toxic to the adjacent tissue surrounding the</p> <p>5 product?</p> <p>6 A. I've not opined that they're toxic to</p> <p>7 the tissue. My opinions is limited to that they</p> <p>8 are being depleted during this oxidation. That was</p> <p>9 my opinion in the report.</p> <p>10 Q. And, Doctor, can you tell us at what</p> <p>11 point in time these antioxidants are depleted?</p> <p>12 A. Again, it's unpredictable. It's --</p> <p>13 it's -- the oxidation reactions happen and when the</p> <p>14 antioxidants are depleted, when the degradation</p> <p>15 starts, all of these events are -- are</p> <p>16 unpredictable. That's why -- that's part of my</p> <p>17 opinion, that that's a problem, that that needs to</p> <p>18 be controlled.</p> <p>19 Q. Doctor, we were talking about physical</p> <p>20 properties of mesh in -- just a minute ago.</p> <p>21 Have you ever tested the physical</p> <p>22 properties of the mesh in any of these nine</p> <p>23 products, such as durability?</p> <p>24 A. What do you mean by "durability"?</p>
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<p>1 have any research grants on that. It's not what I</p> <p>2 do. I mean, I -- I can't -- I -- I -- I don't have</p> <p>3 funding to answer that question, so I haven't done</p> <p>4 that.</p> <p>5 Q. And, Doctor, can you tell us what the</p> <p>6 rate is for the antioxidants allegedly depleting</p> <p>7 from each of these nine products?</p> <p>8 A. Again, I thought I answered that. I</p> <p>9 haven't measured the degradation of the</p> <p>10 antioxidants in the -- in the PROLENE other than</p> <p>11 those Ethicon studies that reported loss of</p> <p>12 antioxidants from oxidized polypropylene. That was</p> <p>13 the study that I was relying on, my opinions, one</p> <p>14 of the studies.</p> <p>15 Q. And, Doctor, it's fair to say that you</p> <p>16 have never tested the effect antioxidants have, in</p> <p>17 vivo, on Ethicon's nine products that we're here</p> <p>18 about today on?</p> <p>19 MR. BOWMAN: Object to form.</p> <p>20 THE WITNESS: I've not looked at the</p> <p>21 antioxidant depletion in these products, in vitro</p> <p>22 or in vivo.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Doctor, do you have any evidence, as we</p>	<p>1 Q. The physical property of durability.</p> <p>2 A. I mean --</p> <p>3 MR. BOWMAN: Object to form.</p> <p>4 THE WITNESS: How are you defining</p> <p>5 that?</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Sir, have you ever -- have you ever</p> <p>8 heard the word "durability" before as a polymer</p> <p>9 scientist?</p> <p>10 A. Yeah, I've heard -- I've heard the</p> <p>11 word, but it would help me if you would --</p> <p>12 Q. Well, my question is --</p> <p>13 A. -- tell me the definition.</p> <p>14 Q. -- using your definition, have you ever</p> <p>15 tested the durability of the mesh of any of these</p> <p>16 nine products?</p> <p>17 A. I mean, I --</p> <p>18 MR. BOWMAN: And I just want to stress</p> <p>19 right here this is asked and answered. He already</p> <p>20 testified that he hasn't tested any exemplar meshes</p> <p>21 or anything about this -- that was before the last</p> <p>22 break. I just want to keep moving. We've only got</p> <p>23 about an hour left. I mean, I don't want to spend</p> <p>24 20 minutes on this if we can help it. But that's</p>

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<p>1 my opinion.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Doctor, durability, tensile strength,</p> <p>4 elongation, toughness, Young's modulus, have you</p> <p>5 ever studied those physical properties of the mesh</p> <p>6 in any of these nine products?</p> <p>7 A. No. As I've said, I've not tested</p> <p>8 these meshes, these nine meshes, these nine</p> <p>9 products, other than the work we did with the TVT</p> <p>10 on the molecular weight analysis and the IR with</p> <p>11 Dr. Dunn. That's what we did.</p> <p>12 Q. But, Doctor, have you done any tests,</p> <p>13 tests, on any of these nine products that can be</p> <p>14 repeated and confirmed?</p> <p>15 A. Well, I just answered your question, I</p> <p>16 thought. We did FTIR, and we did the molecular</p> <p>17 weight analysis, I believe, on the TVT a couple</p> <p>18 years ago.</p> <p>19 Q. And you're talking about --</p> <p>20 A. It was one of Dr. Dunn's earlier</p> <p>21 reports.</p> <p>22 Q. Right. But you're talking about the</p> <p>23 FTIR analysis --</p> <p>24 A. No, I'm not talking about that. I'm</p>	<p>1 A. Yes.</p> <p>2 Q. And forgive me -- and chain scission</p> <p>3 also produces carbonyl bands, correct?</p> <p>4 A. It's in the report, that -- that --</p> <p>5 hydrox- -- hydroperoxide and carbonyl groups result</p> <p>6 in the chain --</p> <p>7 (Reporter interruption for</p> <p>8 clarification.)</p> <p>9 THE WITNESS: Yeah. So it's in the</p> <p>10 report that -- that -- I'll just keep it simple.</p> <p>11 The carbonyl groups are part of the oxidation</p> <p>12 process.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. Right. But you've never seen a</p> <p>15 carbonyl band on an FTIR from any of the nine</p> <p>16 products after it's been implanted in vivo, have</p> <p>17 you?</p> <p>18 A. After it's been implanted in vivo, I've</p> <p>19 not -- as I said, I've not tested explant on those</p> <p>20 nine products. So I have not done that.</p> <p>21 Q. Doctor, you'll -- you -- when you were</p> <p>22 preparing for this litigation, you understood that</p> <p>23 PROLENE is what sutures are made out of, correct?</p> <p>24 A. Some sutures. I mean, PROLENE is a --</p>
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<p>1 talking about exemplars. I'm talking about --</p> <p>2 well, okay. So this study, too, we -- we did the</p> <p>3 FTIR and the SEM and --</p> <p>4 Q. But you're deferring to Dr. Dunn on the</p> <p>5 FTIR and SEM for that -- for the study marked as</p> <p>6 Exhibit 3, aren't you?</p> <p>7 A. For the details of the experiments?</p> <p>8 Q. Correct.</p> <p>9 A. Yeah. We talked about that already.</p> <p>10 Multiple times.</p> <p>11 MR. BOWMAN: If can I just clear</p> <p>12 something up for you.</p> <p>13 MR. HUTCHINSON: (Indicating.)</p> <p>14 MR. BOWMAN: There was some molecular</p> <p>15 weight testing done for an AMS report that was like</p> <p>16 2013 or 2014. And that got into -- they got into</p> <p>17 that in the very first deposition that he had</p> <p>18 taken. I can produce it to you, whatever you like,</p> <p>19 but all that stuff's already been turned over and</p> <p>20 discussed is my understanding.</p> <p>21 MR. HUTCHINSON: Okay.</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. And I may have asked this already. But</p> <p>24 chain scission lowers molecular weight, doesn't it?</p>	<p>1 is the trademark name that Ethicon has given to its</p> <p>2 polypropylene --</p> <p>3 Q. Right. And do you know how long --</p> <p>4 A. -- formulation.</p> <p>5 Q. And do you know how long Ethicon</p> <p>6 sutures have been on the market?</p> <p>7 A. Since the '60s.</p> <p>8 Q. Do you have any criticisms of Ethicon</p> <p>9 sutures?</p> <p>10 MR. BOWMAN: Object to form.</p> <p>11 THE WITNESS: Criticisms? That's -- I</p> <p>12 mean, this report is about mesh. It's not about</p> <p>13 sutures.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Okay. But your report is also about</p> <p>16 PROLENE, correct?</p> <p>17 A. Yes. There's PROLENE --</p> <p>18 Q. And sutures are made out of PROLENE,</p> <p>19 aren't they?</p> <p>20 A. They can be. Some sutures are made out</p> <p>21 of PROLENE.</p> <p>22 Q. And do you have any criticisms of</p> <p>23 sutures made out of PROLENE, as you sit here today?</p> <p>24 MR. BOWMAN: Object to form.</p>

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<p>1 THE WITNESS: I mean, PROLENE sutures</p> <p>2 are also made of polypropylene. I would believe</p> <p>3 they will oxidize and degrade as well. So I think</p> <p>4 that tells us something about what the mesh will</p> <p>5 do. But I'm not opining about the effects of</p> <p>6 sutures and the failure of sutures or -- I'm --</p> <p>7 I'm -- the report's about pelvic mesh --</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. I understand that.</p> <p>10 A. -- made of PROLENE.</p> <p>11 Q. And you're --</p> <p>12 A. I'm not clear what you're asking me.</p> <p>13 I'm sorry.</p> <p>14 Q. You're opining about the failure of</p> <p>15 PROLENE mesh, aren't you?</p> <p>16 A. Yeah. I mean, I -- yes.</p> <p>17 Q. All right. Do you -- do you have</p> <p>18 any -- do you have any criticisms of Ethicon's</p> <p>19 PROLENE sutures, is my question?</p> <p>20 A. I think I'm hung up on the word</p> <p>21 "criticisms." Could you --</p> <p>22 Q. Well, Doctor, are you --</p> <p>23 A. -- could you be a little more --</p> <p>24 Q. I cannot.</p>	<p>1 Q. I understand. I understand that,</p> <p>2 Doctor.</p> <p>3 A. I'm really struggling here.</p> <p>4 Q. But is your opinion -- is it your</p> <p>5 opinion that every person who has ever had a</p> <p>6 PROLENE suture has oxidized material in their body?</p> <p>7 MR. BOWMAN: Object to form.</p> <p>8 THE WITNESS: I believe that PROLENE is</p> <p>9 made from polypropylene. It will oxidize in the</p> <p>10 body. The chemistry, the biology of the</p> <p>11 inflammatory response tells us these reactions are</p> <p>12 going on. It's the clinical implications of those</p> <p>13 reactions that are different. And I'm not speaking</p> <p>14 about that with regard to sutures. It's about with</p> <p>15 regard to the mesh.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. I understand that, Doctor. But my</p> <p>18 question is, is it your opinion that every person</p> <p>19 who has a PROLENE suture has oxidized material in</p> <p>20 their body?</p> <p>21 MR. BOWMAN: Object to form. Asked and</p> <p>22 answered.</p> <p>23 THE WITNESS: I believe that I answered</p> <p>24 it. The material --</p>
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<p>1 A. Okay.</p> <p>2 Q. All right. I cannot.</p> <p>3 Do you have any criticisms -- that word</p> <p>4 speaks for itself -- of Ethicon's PROLENE sutures?</p> <p>5 A. But "criticisms" is a broad word. I --</p> <p>6 I believe that PROLENE sutures oxidize and degrade</p> <p>7 just like the mesh but --</p> <p>8 Q. Have you -- well, what --</p> <p>9 A. Can I finish my answer, please?</p> <p>10 Q. Yes.</p> <p>11 A. I'm hoping my answer will make it go</p> <p>12 away. But -- the -- it's implanted in a different</p> <p>13 part of the body. It's -- it's a suture. It's not</p> <p>14 a wo- -- you know, a multi -- it's not a -- it's</p> <p>15 not a mesh. It's a suture. And so the</p> <p>16 inflammatory response could be different. Location</p> <p>17 in the body is different. The -- the chemical</p> <p>18 reactions are going to be the same.</p> <p>19 Q. Okay.</p> <p>20 A. But the clinical implications are</p> <p>21 different. And I'm not opining about the clinical</p> <p>22 implications of oxidation and degradation on</p> <p>23 PROLENE sutures used -- single fiber monofilaments</p> <p>24 used as sutures. Is that --</p>	<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Respectfully, you haven't.</p> <p>3 A. I have.</p> <p>4 Q. My question is about PROLENE sutures.</p> <p>5 MR. BOWMAN: He did -- he did just</p> <p>6 answer that question.</p> <p>7 THE WITNESS: I just answered that.</p> <p>8 PROLENE sutures are made out of polypropylene, and</p> <p>9 they will be subject to the same oxidation</p> <p>10 reactions as -- how much oxidized compared to mesh,</p> <p>11 I don't know. I'm not talking about that. But</p> <p>12 it's implanted at a different point in the body.</p> <p>13 It's a single fiber instead of a woven mesh. But</p> <p>14 it's -- because it's polypropylene, I believe it</p> <p>15 still will oxidize. It's just the extent of those</p> <p>16 reactions may be very different because the</p> <p>17 inflammatory response may be different. I --</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. Have you investigated why there's been</p> <p>20 a long-term effective use of PROLENE sutures in the</p> <p>21 body?</p> <p>22 MR. BOWMAN: Object to form.</p> <p>23 THE WITNESS: Can you repeat it,</p> <p>24 please. I'm -- could you repeat the question?</p>

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<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Have you investigated why there's been</p> <p>3 a long-term effective use of PROLENE sutures in the</p> <p>4 body?</p> <p>5 MR. BOWMAN: Object to form.</p> <p>6 THE WITNESS: I don't know how to</p> <p>7 answer that. I've looked at PROLENE sutures.</p> <p>8 There are papers that I've cited. There's Ethicon</p> <p>9 studies about PROLENE sutures that I've looked at.</p> <p>10 And I believe those studies point to evidence of</p> <p>11 oxidation and degradation like I've been</p> <p>12 testifying.</p> <p>13 But the -- the effects of the oxidation</p> <p>14 of a PROLENE suture are going to be different than</p> <p>15 for a PROLENE mesh. It's implanted in a different</p> <p>16 part of the body. It's a different type of device.</p> <p>17 So I don't think you can necessarily infer that the</p> <p>18 safety record with PROLENE sutures translates to</p> <p>19 the mesh.</p> <p>20 (Whereupon Exhibit 6 was marked as an</p> <p>21 exhibit.)</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. Handing you what we'll mark as Exhibit</p> <p>24 6 to your deposition. And by the way, before we</p>	<p>1 implanted in their body has oxidized material in</p> <p>2 their body?</p> <p>3 A. Again, I would say how I answered that</p> <p>4 before, that these reactions are ongoing. It's</p> <p>5 reasonable to expect that that material would be</p> <p>6 oxidized. It's just the extent and the clinical</p> <p>7 implications of that are very different because</p> <p>8 it's in a different part of the body.</p> <p>9 Q. Okay. So if I -- I'm just trying to</p> <p>10 understand your answer. But it's your testimony</p> <p>11 that every person that has a PROLENE hernia mesh</p> <p>12 has oxidized material in their body; it's just to</p> <p>13 what extent; is that a fair summary?</p> <p>14 A. To what extent? I would -- I would say</p> <p>15 that --</p> <p>16 Q. No. My -- I'm asking is that a fair</p> <p>17 summary of your testimony?</p> <p>18 A. Could you say it again?</p> <p>19 Q. I did it so good the first time.</p> <p>20 A. Perhaps. But I want to be very clear</p> <p>21 about what I'm saying.</p> <p>22 Q. Let's be clear. Is it your testimony</p> <p>23 that every person who has a PROLENE hernia mesh has</p> <p>24 oxidized material in their body; it's just a matter</p>
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<p>1 move on, Exhibit 5 remains blank, does it not?</p> <p>2 A. I didn't write anything on Exhibit 5.</p> <p>3 Q. This is the -- Exhibit 6 is the Imel</p> <p>4 article that you cite --</p> <p>5 A. Okay.</p> <p>6 Q. -- in your report. You've seen this,</p> <p>7 Doctor, correct?</p> <p>8 A. Yes.</p> <p>9 Q. And the first paragraph, first sentence</p> <p>10 says, "Polypropylene has been used as a mesh for</p> <p>11 hernia repairs since 1958."</p> <p>12 My question, sir, is do you have any</p> <p>13 criticisms of Ethicon's hernia mesh?</p> <p>14 A. My -- my opinions about hernia mesh are</p> <p>15 similar to the sutures. It's implanted in a</p> <p>16 different part of the body. Because it's made from</p> <p>17 polypropylene, it will be subjected to these same</p> <p>18 reactions. But because it's in a different part of</p> <p>19 the body, the clinical implications are different,</p> <p>20 and that's not the subject of my report, what</p> <p>21 happens to a hernia mesh if it's oxidized and</p> <p>22 degraded. That's not --</p> <p>23 Q. Sir, is it your testimony that every</p> <p>24 person has -- that has a hernia PROLENE mesh</p>	<p>1 of to what extent that oxidation has occurred,</p> <p>2 correct?</p> <p>3 A. I want to be very clear about this.</p> <p>4 I -- the science -- the science tells us that</p> <p>5 this -- you would expect this material to oxidize.</p> <p>6 I've not measured it, but I believe the science</p> <p>7 tells us that will happen. And to what extent is</p> <p>8 going to depend on other factors. I -- I -- it's</p> <p>9 possible -- I can't predict it. It's</p> <p>10 unpredictable, the extent of the oxidation and the</p> <p>11 clinical significance. But I believe that the</p> <p>12 chemistry, to a reasonable degree of scientific</p> <p>13 certainty, tells us that these materials will</p> <p>14 oxidize when implanted in the body.</p> <p>15 Q. And every person that has a hernia mesh</p> <p>16 that's made out of PROLENE has oxidized material in</p> <p>17 their body; it's just a -- it's just a matter of to</p> <p>18 what degree; is that fair?</p> <p>19 A. I mean, when exactly these reactions</p> <p>20 start is not exactly clear, so there is some time</p> <p>21 that it takes to happen. But, you know, I believe</p> <p>22 these materials will oxidize. It's just --</p> <p>23 Q. How long does it take to happen?</p> <p>24 A. It's unpredictable. It depends on the</p>

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<p>1 anatomic site. It depends possibly on the patient.</p> <p>2 It depends on lots of factors, but it's something</p> <p>3 that you can't predict, and it's something you</p> <p>4 can't design for.</p> <p>5 Q. If we look at Exhibit 6 to your</p> <p>6 deposition --</p> <p>7 A. Okay.</p> <p>8 Q. -- none of the specimens that Imel,</p> <p>9 I-m-e-l, studied were PROLENE, were they?</p> <p>10 A. These were Boston Scientific meshes, so</p> <p>11 they -- they did not include PROLENE.</p> <p>12 Q. And when a medical device is first</p> <p>13 implanted in the body, it comes in contact with</p> <p>14 body fluids, fair to say?</p> <p>15 A. Yes.</p> <p>16 Q. And macrophages are some of those body</p> <p>17 fluids.</p> <p>18 A. Well, macrophage is a cell, not a</p> <p>19 fluid.</p> <p>20 Q. Okay. Or -- or body -- body material.</p> <p>21 And macrophages contain proteins, correct?</p> <p>22 A. Well, I mean, all cells contain</p> <p>23 proteins, but it's a -- it's a cell. I mean, a</p> <p>24 cell --</p>	<p>1 protein can --</p> <p>2 Q. That's with a D.</p> <p>3 A. With a D. Yeah. Sorry.</p> <p>4 Can the adsorbed proteins be removed</p> <p>5 mechanically? Is that what you mean?</p> <p>6 Q. Yes, sir.</p> <p>7 A. Probably not. It's --</p> <p>8 Q. It -- it would be a chemical -- it</p> <p>9 would have to be a chemical reaction or a chemical</p> <p>10 protocol to remove the proteins; is that right?</p> <p>11 A. Typically, you would -- you could</p> <p>12 desorb them, you could break them with a</p> <p>13 proteinase. Yeah. Something not mechanical.</p> <p>14 Q. Okay. And, Doctor, do you know how to</p> <p>15 remove proteins from a medical device after it's</p> <p>16 taken out of the body?</p> <p>17 A. Well, in my work, we're more concerned</p> <p>18 with removing cells. So we'll use different</p> <p>19 enzymes and -- and materials to remove the cells</p> <p>20 from the material.</p> <p>21 Q. Do you know how to clean and remove</p> <p>22 proteins from an explanted piece of mesh, from a</p> <p>23 chemical standpoint?</p> <p>24 A. I thought I answered it; but, I mean, I</p>
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<p>1 Q. But -- but we can agree that proteins</p> <p>2 adsorb to the surface of the medical implant,</p> <p>3 correct?</p> <p>4 A. Well, the -- the proteins adsorb to</p> <p>5 facilitate cell attachment. I mean, that the</p> <p>6 adsorbed proteins facilitate --</p> <p>7 Q. And --</p> <p>8 A. -- the attachment to cells.</p> <p>9 Q. And that occurs -- and that reaction</p> <p>10 occurs within seconds of the implant; is that</p> <p>11 right?</p> <p>12 A. Proteins adsorb very -- fast, yeah.</p> <p>13 Q. Can proteins be removed manually from</p> <p>14 the explant?</p> <p>15 MR. BOWMAN: Object to form.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Once it's taken out of the body?</p> <p>18 A. Manually? What do you mean by</p> <p>19 "manually"?</p> <p>20 Q. Can they be scrubbed off? Can they be</p> <p>21 removed with tweezers?</p> <p>22 A. I mean, tissue can.</p> <p>23 Q. But the protein, sir, is my question.</p> <p>24 A. The adsorbed proteins? I mean, this</p>	<p>1 know Dr. Timms used proteinase. A lot of people</p> <p>2 are using --</p> <p>3 Q. I know what they do.</p> <p>4 A. Yeah.</p> <p>5 Q. But I'm asking what you know.</p> <p>6 A. Well, I haven't specifically --</p> <p>7 Q. Okay.</p> <p>8 A. -- done that. Like I said, I'm</p> <p>9 typically removing cells. But you still have to</p> <p>10 digest the matrix. So we add these types of --</p> <p>11 because the cells are embedded in some matrix, and</p> <p>12 if you want the cells, you have to digest the</p> <p>13 matrix.</p> <p>14 Q. And, Doctor, you'll agree that an</p> <p>15 increased layer of proteins can build up on a</p> <p>16 foreign body object over time?</p> <p>17 A. Yeah, protein adsorption is typically</p> <p>18 going to reach some equilibrium. Now --</p> <p>19 Q. But it will build up over time. The</p> <p>20 proteins will build up on a medical device over</p> <p>21 time?</p> <p>22 A. I would like to be a little more</p> <p>23 specific in my answer, if I could. The -- the</p> <p>24 proteins will adsorb which can facilitate cell</p>

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<p>1 attachment and cells can deposit matrix and that 2 combined -- it's a very complex event. It's not -- 3 it's not a -- you know, I -- I guess -- I don't 4 know that -- I mean, my understanding of protein 5 adsorption is, if you're going to reach some 6 equilibrium, there's going to be some competitive 7 adsorption with different proteins. But the 8 over-time part, to me, would be more matrix 9 deposition by the cells.</p> <p>10 Q. On page 1 of Exhibit 6 --</p> <p>11 A. Okay.</p> <p>12 Q. -- we talked about polypropylene being 13 used as a mesh for hernia repairs since the 1950s.</p> <p>14 Doctor, does the pelvic region have 15 more reactive oxygen species than the abdomen? Or 16 do you know?</p> <p>17 MR. BOWMAN: Object to form.</p> <p>18 THE WITNESS: There have been some -- 19 there's -- I know there's one paper that's been 20 published about the increased prevalence of the -- 21 of ROS, things like peroxides in the vaginal space.</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. But can you quantify reactive oxygen 24 species found in the pelvic region?</p>	<p>1 peroxides that are secreted in vivo?</p> <p>2 A. Well, maybe we can make this a little 3 faster by -- all of these reactive oxygen 4 species -- how much is secreted by adherent cells 5 on the mesh, that's not been measured, but, again, 6 it's a very localized environment. There's an 7 adherent cell on the surface and that 8 microenvironment is different from the broader 9 tissue microenvironment.</p> <p>10 So it's difficult to know exactly what 11 the composition of that -- we know what's in it. 12 That's why the simulated oxidation test was 13 developed. But the exact concentrations of all 14 those species are difficult to know.</p> <p>15 Q. In fact, you don't know those exact 16 concentrations of all those species sitting here 17 today, do you?</p> <p>18 MR. BOWMAN: Asked and answered.</p> <p>19 THE WITNESS: I mean, I thought I 20 answered it. Not for -- I mean, not -- for this 21 adherent macrophage on the surface of the 22 polypropylene, I don't -- I don't know what the 23 concentrations of all these relative species are, 24 but they're there.</p>
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<p>1 A. I've -- I mean, I've not done that, but 2 I believe this paper -- I would have to review the 3 paper to see exactly what -- but I believe it has 4 been looked at.</p> <p>5 Q. What's the name of the paper?</p> <p>6 A. I just can't remember right now.</p> <p>7 Q. Is it cited in your report that we've 8 marked as Exhibit 2 to your deposition?</p> <p>9 A. It's probably on the reliance list. I 10 would have to check. I just don't remember. I 11 wasn't -- yeah.</p> <p>12 Q. Doctor, sitting here today, can you 13 quantify -- without looking at your literature, can 14 you quantify the reactive oxygen species found in 15 the pelvic region?</p> <p>16 A. I've not done that.</p> <p>17 Q. Doctor, can you tell us the amount of 18 peroxides that are secreted in vivo?</p> <p>19 A. Well, it's not just peroxides. It's 20 hydroxyl radicles, hypochlorous acid. There's a 21 lot of these reactive oxygen species that are 22 secreted by different types of cells.</p> <p>23 Q. Okay. Well, let's take -- let's take 24 one by one. Can you tell us the amount of</p>	<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. But -- and, sir, do you have -- can you 3 give us a percentage?</p> <p>4 A. I -- I -- I -- I don't know. I'd have 5 to look at some papers. I don't know the -- the 6 exact composition of that.</p> <p>7 Q. And how -- how do they -- how does that 8 compare to 30 percent hydrogen peroxide?</p> <p>9 A. Well, that's -- that test is -- you're 10 referring to -- okay. I'm confused. Are you 11 referring to just 30 percent hydrogen peroxide or 12 with the cobalt catalyst? I'm not -- I'm not 13 sure --</p> <p>14 Q. The 20 percent. Let's use 20 percent.</p> <p>15 A. Just the hydrogen peroxide?</p> <p>16 Q. Uh-huh.</p> <p>17 A. Well, I mean, that test was done to 18 give some estimate of what the effects could be.</p> <p>19 Q. And -- and, Doctor, you'll agree that 20 20 percent hydrogen peroxide is higher than what is 21 usually seen in a clinical setting in the body?</p> <p>22 A. Well, I think that's a very vaguely 23 stated -- the -- again, these -- these compositions 24 are in a -- are in a privileged microenvironment.</p>

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<p>1 There's a pocket between the adherent macrophage</p> <p>2 and the surface of the material.</p> <p>3 Q. Right.</p> <p>4 A. So the composition there in that</p> <p>5 microenvironment is different than -- and that's</p> <p>6 the concentration that matters because that's what</p> <p>7 the polypropylene is exposed to.</p> <p>8 Q. I understand.</p> <p>9 A. So the concentration everywhere else in</p> <p>10 the body doesn't really matter --</p> <p>11 Q. Doctor --</p> <p>12 A. -- as much.</p> <p>13 Q. -- do you have any idea how much</p> <p>14 hydrogen peroxide is produced by the body in a</p> <p>15 foreign response -- foreign -- in a foreign body</p> <p>16 response to any of these nine products that we're</p> <p>17 here today on?</p> <p>18 A. Again, I thought I've answered that.</p> <p>19 It's this -- there's this microenvironment, and how</p> <p>20 much hydrogen peroxide is in there is -- is not --</p> <p>21 I don't -- I can't -- I just can't answer that</p> <p>22 right now without looking at some studies.</p> <p>23 Q. Okay. And, Doctor, what studies would</p> <p>24 you need to look at?</p>	<p>1 over the body.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Okay. And, Doctor, can you tell us how</p> <p>4 much hydrogen peroxide would be needed to oxidize</p> <p>5 PROLENE in vivo?</p> <p>6 MR. BOWMAN: Object to form.</p> <p>7 THE WITNESS: Again, it's a question of</p> <p>8 rate. The more hydrogen peroxide, other oxidative</p> <p>9 species, the faster it's going to occur. What</p> <p>10 exactly those concentrations are, I don't know that</p> <p>11 it's been studied for polypropylene oxidation,</p> <p>12 what -- what those concentrations are.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. And I'm not asking about polypropylene</p> <p>15 oxidation. I'm talking about PROLENE oxidation.</p> <p>16 So let's be clear.</p> <p>17 A. PROLENE's --</p> <p>18 Q. Hold on just a minute. Let me finish</p> <p>19 my question.</p> <p>20 A. I thought you were finished.</p> <p>21 Q. Doctor, can you tell us how much</p> <p>22 hydrogen peroxide would cause PROLENE to oxidize in</p> <p>23 vivo?</p> <p>24 MR. BOWMAN: Object to form.</p>
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<p>1 A. I'd have to -- I just don't -- I'd have</p> <p>2 to look for some papers on that. I don't -- I</p> <p>3 don't -- I don't know -- I don't have it in my</p> <p>4 memory what --</p> <p>5 Q. Are those paper on your reliance list?</p> <p>6 A. I don't know.</p> <p>7 Q. Doctor, you'll agree that 20 percent</p> <p>8 hydrogen peroxide is higher than what is usually</p> <p>9 seen in a clinical setting?</p> <p>10 A. I'm not going to agree with that. You</p> <p>11 can keep asking it over and over. I'm not going to</p> <p>12 agree with it. Because "clinical setting" is a</p> <p>13 vague term.</p> <p>14 Clinical setting, are you talking about</p> <p>15 everywhere in the body or are you talking about</p> <p>16 that specific microenvironment between the cell and</p> <p>17 the biomaterial? I mean, it's -- it's -- it's too</p> <p>18 vague of a question.</p> <p>19 Q. Do you know how many micromoles of</p> <p>20 hydrogen peroxide are found in the body?</p> <p>21 MR. BOWMAN: Object to form.</p> <p>22 THE WITNESS: Again, it's too vague of</p> <p>23 a question. What's in the body -- what matters is</p> <p>24 what's in that microenvironment, not what's all</p>	<p>1 THE WITNESS: I would answer it the</p> <p>2 same -- there's that microenvironment and how much</p> <p>3 hydrogen peroxide is in there is -- I -- I don't</p> <p>4 know. If there's some, it will oxidize. But if</p> <p>5 it's going to -- it's a question of concentration.</p> <p>6 The more that's there, the more it's going to</p> <p>7 oxidize.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. You can't tell us how much hypochlorous</p> <p>10 acids would cause PROLENE to oxidize in the body,</p> <p>11 can you?</p> <p>12 MR. BOWMAN: Object to form. He's --</p> <p>13 he's already made it clear that he's talking about</p> <p>14 concentrations and not --</p> <p>15 MR. HUTCHINSON: Understood.</p> <p>16 Understood.</p> <p>17 MR. BOWMAN: Okay.</p> <p>18 MR. HUTCHINSON: Understood.</p> <p>19 THE WITNESS: I'm just going to keep</p> <p>20 saying --</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. Same question with hydrochloric acid.</p> <p>23 A. So hydrochloric acid, again, it's --</p> <p>24 Q. Can you tell us how much would cause</p>

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<p>1 PROLENE to oxidize?</p> <p>2 A. Well, I don't know that hydrochloric</p> <p>3 acid would cause oxidation. I mean, polypropylene</p> <p>4 is relatively resistant to acids and bases. It's</p> <p>5 the oxidizers that it's not. So I would say that</p> <p>6 all of these reactive oxygen species are -- are --</p> <p>7 you know, they're present in that privileged</p> <p>8 microenvironment, and they're going to cause</p> <p>9 oxidation. That's what we know.</p> <p>10 Q. But you can't tell us how much is</p> <p>11 required to cause oxidation, can you, is my</p> <p>12 question?</p> <p>13 MR. BOWMAN: Object to the form.</p> <p>14 THE WITNESS: I feel like I've answered</p> <p>15 it. If it's there, it will cause oxidation.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. I understand.</p> <p>18 A. It's a question of the rate and the</p> <p>19 extent.</p> <p>20 Q. But can you tell us how -- how much</p> <p>21 will cause oxidation? That's my question.</p> <p>22 A. If there's some there, it will cause</p> <p>23 oxidation. It's just a question of the extent. So</p> <p>24 if there's more or less, there will be more or less</p>	<p>1 Q. Can you answer that question, Doctor?</p> <p>2 A. I'm going to answer it the same way</p> <p>3 I've been answering it. That if there is reactive</p> <p>4 oxygen species in that privileged microenvironment,</p> <p>5 there will be -- you would expect there to be</p> <p>6 oxidation going on, and it's a question of</p> <p>7 concentration. The more that's there, the more</p> <p>8 oxidation you're going to get.</p> <p>9 Q. And can you quantify -- and strike</p> <p>10 that.</p> <p>11 And can you quantify that</p> <p>12 concentration?</p> <p>13 MR. BOWMAN: Object to the form. Asked</p> <p>14 and answered.</p> <p>15 THE WITNESS: I don't know, off the top</p> <p>16 of my head, by my memory, what the concentrations</p> <p>17 of those reactive oxygen species are. I think you</p> <p>18 asked me about that already. But I know that</p> <p>19 they're there. And I -- and that -- they're there.</p> <p>20 Those reactions would be expected to occur.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. Doctor, let's go back to Sanotox R and</p> <p>23 DLTDP. Do you have criticisms of Ethicon for using</p> <p>24 those two specific antioxidants in their</p>
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<p>1 oxidation. But if the reactive oxygen species are</p> <p>2 there, you would expect these reactions to be going</p> <p>3 on. I guess I'm really. . .</p> <p>4 Q. That's fine.</p> <p>5 MR. HUTCHINSON: Move to strike as</p> <p>6 nonresponsive.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. My question to you, sir, is can you</p> <p>9 tell us how much would cause PROLENE to oxidize in</p> <p>10 the body?</p> <p>11 A. And I believe I've answered --</p> <p>12 MR. BOWMAN: Objection --</p> <p>13 THE WITNESS: -- that question multiple</p> <p>14 times.</p> <p>15 (Simultaneous speaking.)</p> <p>16 (Reporter interruption for</p> <p>17 clarification.)</p> <p>18 MR. BOWMAN: I have to object as</p> <p>19 compound and vague. He's already made it clear</p> <p>20 that he's asking -- he wants you to include</p> <p>21 concentrations in -- in the amount of material</p> <p>22 that's -- that's going to be oxidized, that kind of</p> <p>23 thing.</p> <p>24 BY MR. HUTCHINSON:</p>	<p>1 formulation of PROLENE?</p> <p>2 A. I believe my opinion on this matter is</p> <p>3 that those antioxidants were added to protect the</p> <p>4 polypropylene during the manufacturing process and</p> <p>5 whether or not they're doing anything -- protecting</p> <p>6 any in vivo oxidation was not looked at very much.</p> <p>7 There are some studies where they show depletion of</p> <p>8 oxidation in the -- depletion of antioxidants in</p> <p>9 the oxidized polypropylene on the surface.</p> <p>10 Q. Okay. But my question is are you</p> <p>11 criticizing Ethicon for using DLTPD and Sanotox R</p> <p>12 in the formulation of PROLENE?</p> <p>13 MR. BOWMAN: Object to form.</p> <p>14 THE WITNESS: Are you asking</p> <p>15 criticizing the selection of those?</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. (Indicating yes.)</p> <p>18 A. I don't know how to answer it, other</p> <p>19 than I did. Those antioxidants were chosen for</p> <p>20 stabilization during manufacturing and storage, not</p> <p>21 for in vivo use. That's -- that's my opinion.</p> <p>22 Q. So --</p> <p>23 A. And they're well known to stabilize --</p> <p>24 I mean, they're well known stabilizers for</p>

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<p>1 manufacturing purposes, but not for -- necessarily</p> <p>2 for in vivo oxidation.</p> <p>3 Q. Doctor, but that's not my question.</p> <p>4 Are you criticizing Ethicon for selecting Sanotex R</p> <p>5 and DLTD as two antioxidants used in the</p> <p>6 formulation of PROLENE?</p> <p>7 MR. BOWMAN: Object to form. Asked and</p> <p>8 answered.</p> <p>9 THE WITNESS: Again, I believe I've</p> <p>10 answered it. I'm not --</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. And in all due respect -- in all due</p> <p>13 respect, Doctor, you haven't. I'm just -- do you</p> <p>14 criticize Ethicon? That's all my question --</p> <p>15 MR. BOWMAN: He did answer that today,</p> <p>16 and he's already testified about this in the Huskey</p> <p>17 case. And -- but he has --</p> <p>18 THE WITNESS: I'll try one more time.</p> <p>19 So those two antioxidants are well known for</p> <p>20 protecting polypropylene during manufacturing. I'm</p> <p>21 not --</p> <p>22 MR. HUTCHINSON: And move it strike as</p> <p>23 nonresponsive.</p> <p>24 BY MR. HUTCHINSON:</p>	<p>1 complex matter. There are many different</p> <p>2 combinations that can be used. Just because a</p> <p>3 certain set of antioxidants is useful for</p> <p>4 protecting during manufacturing and -- and</p> <p>5 long-term storage doesn't mean they'll be effective</p> <p>6 in the body. That needs to be studied with in vivo</p> <p>7 studies and perhaps testing different</p> <p>8 concentrations, different types of antioxidants.</p> <p>9 My -- my criticism has been that that</p> <p>10 work has not been done, at least to a very</p> <p>11 extensive degree, other than that study that showed</p> <p>12 antioxidant depletion in the -- in the oxidized</p> <p>13 polypropylene.</p> <p>14 Q. Doctor, can you tell us the names of --</p> <p>15 of the antioxidants that you believe Ethicon should</p> <p>16 have used?</p> <p>17 A. I believe I just answered your</p> <p>18 question. I'm not -- I'm not proposing any</p> <p>19 specific set of antioxidants. I'm saying that</p> <p>20 studies should have been done to consider different</p> <p>21 combinations, different formulations other than</p> <p>22 just protecting it during the manufacturing</p> <p>23 process.</p> <p>24 Q. And do you have any alternatives,</p>
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<p>1 Q. I'm not asking you how well known they</p> <p>2 are. I'm asking you if criticize Ethicon for</p> <p>3 selecting --</p> <p>4 A. I was trying to finish. Just let me</p> <p>5 finish.</p> <p>6 Q. All right. But please answer the</p> <p>7 question.</p> <p>8 A. Just --</p> <p>9 Q. Do you criticize Ethicon for selecting</p> <p>10 DLTD and Sanotex R as antioxidants?</p> <p>11 A. I'm -- I'm not criticizing them for</p> <p>12 using those in the manufacturing process. I am</p> <p>13 criticizing the logic that they're going to be</p> <p>14 effective in vivo because that was never really</p> <p>15 looked at carefully.</p> <p>16 Q. Do you have a solution?</p> <p>17 A. I'm not proposing a solution. I'm</p> <p>18 not -- I'm not providing an opinion other than</p> <p>19 that -- that that should be looked at, what -- how</p> <p>20 effective are these antioxidants in vivo. That's</p> <p>21 my opinion.</p> <p>22 Q. And what's the alternative to these</p> <p>23 antioxidants, Doctor?</p> <p>24 A. Well, antioxidants are a -- are a</p>	<p>1 sitting here today, to Sanotex R and DLTD?</p> <p>2 A. I'm not proposing alternatives. Those</p> <p>3 two antioxidants could have been studied in vivo,</p> <p>4 or they could have looked at other antioxidants.</p> <p>5 There -- but -- but that wasn't done. That's --</p> <p>6 that's my opinion, that I've stated many times in</p> <p>7 trial and depositions and courts, and that hasn't</p> <p>8 changed.</p> <p>9 Q. Doctor, if we look the Imel study that</p> <p>10 we've marked as Exhibit 6 --</p> <p>11 A. Exhibit 6, that's -- those are -- I'm</p> <p>12 sorry. You said what? Oh, Imel.</p> <p>13 Q. Yeah. I-m-e-l.</p> <p>14 A. I thought you said animal. Sorry.</p> <p>15 Q. That's okay. Are you there with me?</p> <p>16 A. I am.</p> <p>17 Q. The fibers from these mesh explants</p> <p>18 were not 100 percent cleaned of proteins, were</p> <p>19 they?</p> <p>20 A. I don't know how to answer that. In</p> <p>21 this study, he found regions of oxidized</p> <p>22 polypropylene that had no protein because there was</p> <p>23 no nitrogen present, and he found regions where</p> <p>24 there appeared to be a mix of oxidized</p>

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<p>1 polypropylene and protein. So there were regions 2 where there were still adsorbed proteins, but there 3 are regions where there were not. That's what he 4 reports in the study. 5 Q. Okay. And, Doctor, he also reports in 6 this study a carbonyl peak at 1740; is that right? 7 A. In the IR spectra and his supplemental 8 data, he's seen a carbonyl peak at 1740 that's not 9 in the explants -- I'm sorry -- that's not in 10 the nonimplanted exemplars, but it -- it does 11 appear in the explants. 12 Q. Doctor, do you know where DLTDP has 13 a -- has a FTIR spectra showing up on the -- 14 A. There's some -- 15 Q. -- on the reciprocal centimeter line? 16 A. There is some internal Ethicon 17 documents that reported in that range. 18 Q. In 1740? 19 A. Uh-huh. I think so. 20 Q. Is that a "yes"? 21 A. Yes, that's what I remember. 22 Q. Okay. 23 A. There are some internal Ethicon 24 documents that show depletion, but when they took</p>	<p>1 I mean, it depends on the product and what it's 2 supposed to do, where it's implanted, what -- what 3 the expected response is. 4 MR. HUTCHINSON: Move to strike as 5 nonresponsive. 6 And this is not going to count as my 7 time. I mean, it's a very clear question. 8 BY MR. HUTCHINSON: 9 Q. My question to you is are you aware of 10 any medical device on the market that will never 11 oxidize? 12 A. This is such an extreme question. I 13 don't -- I don't know. I mean, there are -- there 14 are materials that oxidize -- that -- that oxidize 15 very slowly or not much at all that can be 16 measured, but -- I mean, there's a lot of 17 biomedical devices on the market. I haven't looked 18 at that specific question. 19 Q. Can you answer that question, Doctor, 20 sitting here today? 21 A. A device that's never oxidized? I 22 don't know. I mean, I'd have to look into that. 23 This is so broad. It's hard to answer. 24 Q. Doctor, can you tell me the name of a</p>
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<p>1 those IR spectra, they blew them way up so the 2 normal -- the peaks are very small. They're 3 difficult to see. 4 Q. Doctor, have -- and I may have asked 5 you this earlier. Have you ever designed a medical 6 device product? 7 A. Have I ever designed a medical device 8 product? In my research, I work with device 9 companies on -- I have work ongoing in that area. 10 Q. And do any of the products that you 11 have worked on have a lifetime warranty? 12 A. Lifetime warranty? I mean, these are 13 degradable grafts. So they're intended to -- 14 Q. The products that you're working on? 15 A. Yes. 16 Q. Okay. 17 A. So they're intended to be replaced by 18 tissue over time and go away. 19 Q. Doctor, are you aware of any medical 20 product on the market that will never oxidize? 21 A. Wow. That's a really broad question. 22 A product that will never oxidize? I don't know. 23 MR. BOWMAN: Object to form. 24 THE WITNESS: That's so vague. I . . .</p>	<p>1 medical device on the market that will never 2 oxidize? 3 A. And, again, it's a -- it's just a -- I 4 don't know how to answer that. That's a broad 5 question. Never oxidize. I don't -- I don't know. 6 MR. HUTCHINSON: Move to strike 7 everything before "I don't know." 8 BY MR. HUTCHINSON: 9 Q. Doctor, are you aware of any foreign 10 body material that will never oxidize in the body? 11 A. Any foreign body material? 12 Q. That will never oxidize in the body. 13 A. I don't know. Again, it's -- it's 14 extremes of oxidation. I mean, it's -- it's -- 15 these are misleading questions. I don't -- I don't 16 know of any material that just doesn't oxidize. 17 I'd have to -- I don't know. 18 MR. HUTCHINSON: And move to strike 19 everything other than I don't know any material 20 that doesn't oxidize. 21 BY MR. HUTCHINSON: 22 Q. Doctor, can oxidation in pelvic mesh 23 ever be completely eliminated? 24 A. Can oxidation in pelvic mesh be</p>

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<p>1 completely eliminated? I mean, I think it's in my 2 report. No. These -- these antioxidants -- 3 Q. It's not in your report. 4 A. It is in my report. 5 Q. Listen to my question. 6 A. Okay. 7 Q. Can oxidation of pelvic mesh ever be 8 completely eliminated? That's the question. 9 MR. BOWMAN: Object to form. 10 THE WITNESS: I believe it's in my 11 report. I -- the antioxidants are depleted over 12 time. The mesh oxidizes. And the clinical 13 implications are unpredictable. You can't design 14 for it. That's my answer. 15 BY MR. HUTCHINSON: 16 Q. My -- my question is can oxidation of 17 pelvic mesh ever be completely eliminated? 18 A. I just answered it. The antioxidants 19 deplete over time, and the mesh will oxidize as 20 they're depleted, and that's going to lead to these 21 other events that are unpredictable. That's the 22 answer to the question. 23 Q. So it can be completely eliminated in 24 pelvic mesh?</p>	<p>1 can oxidize. 2 BY MR. HUTCHINSON: 3 Q. But can oxidation ever be completely 4 eliminated, sir? 5 A. As the antioxidants are depleted, 6 oxidation of the mesh would be expected to occur. 7 I don't know what else to say. 8 Q. My question is can it ever be 9 completely eliminated? 10 A. As the antioxidants are depleted in the 11 mesh, the polypropylene would oxidize. 12 MR. HUTCHINSON: Move to strike as 13 nonresponsive. 14 BY MR. HUTCHINSON: 15 Q. My question is -- 16 MR. BOWMAN: He's actually answered 17 this question. 18 MR. HUTCHINSON: No, he hasn't. My 19 question is -- 20 MR. BOWMAN: He said he wasn't giving 21 you any -- 22 (Simultaneous speaking.) 23 THE WITNESS: We can sit here for -- 24 (Reporter interruption for</p>
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<p>1 A. I answered the question. I don't 2 really want to play this game. 3 THE WITNESS: Can I -- can we take a 4 break again? I -- 5 BY MR. HUTCHINSON: 6 Q. No. I need the question answered first 7 and then we'll take a break. 8 A. We can answer it for an hour. I'm 9 going to give you the same answer I just gave you. 10 I feel like I've made these opinions very clear. 11 Q. My question is can oxidation of pelvic 12 mesh ever be completely eliminated? Yes or no? 13 MR. BOWMAN: Object to form. 14 THE WITNESS: The antioxidants are 15 depleted. As the antioxidants are depleted, you 16 expect oxidation of the polypropylene in the mesh, 17 which can lead to these other unpredictable events. 18 BY MR. HUTCHINSON: 19 Q. But can it ever be completely 20 eliminated? That is my question. 21 A. The antioxidants are -- 22 MR. BOWMAN: Object to form. 23 THE WITNESS: -- depleted over time. 24 As they're depleted, the polypropylene in the mesh</p>	<p>1 clarification.) 2 THE WITNESS: We can sit here for an 3 hour if you want. I mean, it's over at 1:00. 4 As the antioxidants are depleted -- 5 MR. HUTCHINSON: And move to strike as 6 nonresponsive. 7 THE WITNESS: -- the polypropylene -- 8 BY MR. HUTCHINSON: 9 Q. I'm trying to be respectful to you, 10 Doctor. 11 MR. BOWMAN: No, wait a minute. I need 12 to -- 13 MR. HUTCHINSON: Then we'll take a 14 break. 15 MR. BOWMAN: I need to get my objection 16 on the record. He's already said he's not offering 17 you alternatives. He's telling you what's going on 18 with the pelvic mesh that's involved here. All 19 right? Now I'm going to object as asked an 20 answered. 21 And if you want to rephrase the 22 question, go ahead. 23 MR. HUTCHINSON: All right. 24 BY MR. HUTCHINSON:</p>

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<p>1 Q. I'm asking, Doctor, can it ever 2 be completely -- can oxidation ever be completely 3 eliminated?</p> <p>4 MR. BOWMAN: I'm going to instruct you 5 not to answer.</p> <p>6 THE WITNESS: I'm not going to answer. 7 BY MR. HUTCHINSON:</p> <p>8 Q. Doctor, are you giving any alternatives 9 to PROLENE mesh? And your counsel said no. I just 10 want to make sure, and then we'll take a break.</p> <p>11 MR. BOWMAN: Object to form. 12 BY MR. HUTCHINSON:</p> <p>13 Q. Are you giving any alternatives to 14 PROLENE mesh?</p> <p>15 A. I've not opined that there are 16 alternatives to PROLENE mesh. My opinions relate 17 to what happens to PROLENE implanted in the body.</p> <p>18 Q. And I understand that. I know there's 19 none in your report. But are you giving, here 20 today, any opinions?</p> <p>21 A. I -- I just said that. I'm not giving 22 any opinions about alternatives to PROLENE mesh. 23 I'm stating what happens to PROLENE mesh in the 24 body.</p>	<p>1 changed?</p> <p>2 A. Other than what I said before, I 3 believe more testing could have been done to 4 address the question of oxidation, degradation and 5 the clinical implications of that and bench scale 6 testing, preclinical testing could have been done 7 to answer that question. That's also in my report.</p> <p>8 Q. All right. But outside of more 9 testing -- I want to talk about specifically how 10 you believe Ethicon's nine different products 11 should be significantly changed. Do you have any 12 opinions of how they should be changed?</p> <p>13 A. How they should be changed?</p> <p>14 Q. Yes, sir. These nine different 15 products.</p> <p>16 A. Well, conceptually, they could be made 17 more resistant to in vivo oxidation by looking at 18 the antioxidant package. That could be an 19 improvement. That's consistent with my opinions.</p> <p>20 Q. And, Doctor, how would you make the 21 mesh in these nine products more resistant to in 22 vivo oxidation?</p> <p>23 A. I think it needs to be studied. You 24 would have to do testing to identify an antioxidant</p>
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<p>1 MR. HUTCHINSON: Okay. We can take a 2 break.</p> <p>3 MR. BOWMAN: All right. 4 (Brief recess.)</p> <p>5 MR. HUTCHINSON: Doctor, we're back on 6 the record. Are you ready to go?</p> <p>7 THE WITNESS: Yes. 8 BY MR. HUTCHINSON:</p> <p>9 Q. Is there anything -- have you 10 understood all my questions so far?</p> <p>11 A. Most of them.</p> <p>12 Q. Have you -- is there anything about the 13 testimony that you have given that you would like 14 to change?</p> <p>15 A. No.</p> <p>16 Q. Doctor, do you have any opinions about 17 how Ethicon's nine products should be changed or 18 modified in the way they are manufactured, and if 19 so, how?</p> <p>20 A. Specific to manufacturing, no. I don't 21 have any opinions about the manufacturing of the 22 devices.</p> <p>23 Q. Do you have any opinions about how 24 Ethicon's nine products should be significantly</p>	<p>1 package that's effective in vivo. I -- I don't 2 know a specific package without doing testing.</p> <p>3 Q. Doctor, on -- let's talk about the 4 women on Exhibit Number 1 that you're here to 5 testify for.</p> <p>6 A. Okay. What about the doctors for any 7 of these women? Did any of these doctors commit 8 malpractice by using these Ethicon products in 9 pelvic floor repair?</p> <p>10 MR. BOWMAN: Object to form.</p> <p>11 THE WITNESS: I've not expressed any 12 opinion about the conduct of the doctors in 13 implanting these women. I -- I have no opinion 14 about the doctors.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. And, Doctor, do you believe that these 17 doctors who implanted these Ethicon products in 18 these women did anything wrong?</p> <p>19 MR. BOWMAN: Object to form.</p> <p>20 THE WITNESS: I've not opined that 21 they've done anything wrong. They implanted the 22 device. I don't know how it was implanted. I 23 don't know when. I haven't reviewed the medical 24 records. So I have no way to assess the conduct of</p>

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<p>1 the doctors.</p> <p>2 MR. HUTCHINSON: And, Doctor, we'll</p> <p>3 hand you what we'll mark as Exhibit 7 to your</p> <p>4 deposition.</p> <p>5 (Whereupon Exhibit 7 was marked as an</p> <p>6 exhibit.)</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. You've seen this study before, haven't</p> <p>9 you?</p> <p>10 A. Yes.</p> <p>11 Q. And this is the seven-year dog study</p> <p>12 done by Dan Burkley?</p> <p>13 A. It is.</p> <p>14 Q. And you've relied on this study in</p> <p>15 support of your opinions; is that correct?</p> <p>16 A. Yes.</p> <p>17 Q. And, Doctor, do you -- if you'll look</p> <p>18 with me, please, on page 09888221 -- 221 is the</p> <p>19 last. . .</p> <p>20 A. 09888221?</p> <p>21 Q. 221.</p> <p>22 A. Okay.</p> <p>23 Q. Down there at the bottom, it states</p> <p>24 under "Conclusions": "Comparison of 7-year</p>	<p>1 sampling problem?</p> <p>2 MR. BOWMAN: Object to form.</p> <p>3 THE WITNESS: Well, I'll be more</p> <p>4 specific. They -- they sampled the whole fiber.</p> <p>5 Whereas, the molecular weight loss would be</p> <p>6 expected to occur near the surface of the fiber.</p> <p>7 And so if the bulk of the fiber had not yet</p> <p>8 degraded, you wouldn't see it, but you would still</p> <p>9 see the effects at the surface. You have to sample</p> <p>10 the polypropylene on the surface as they did in</p> <p>11 that human explant study. But in this I think it</p> <p>12 was just the bulk fiber.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. And, Doctor, any time there's a chain</p> <p>15 scission, there's loss of molecular weight; is that</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. And, Doctor, if you look at the</p> <p>19 seven-year dog study, other than -- other than a</p> <p>20 sampling size, do you have any other explanation of</p> <p>21 why --</p> <p>22 MR. HUTCHINSON: On page 221, Counsel.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. -- there was a finding of no molecular</p>
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<p>1 explants to current PROLENE indicate no molecular</p> <p>2 weigh degradation."</p> <p>3 Did I read that correctly?</p> <p>4 A. That's what it says.</p> <p>5 Q. And, Doctor, do you have an explanation</p> <p>6 of why the findings in the Ethicon dog study showed</p> <p>7 no molecular weight degradation?</p> <p>8 MR. BOWMAN: Object to form. Misstates</p> <p>9 the document.</p> <p>10 THE WITNESS: Well, my understanding</p> <p>11 is, what they did in this study, they sampled the</p> <p>12 entire volume of the suture and the molecular</p> <p>13 weight degradation is occurring near the surface,</p> <p>14 in the outer layers. And so they may have not been</p> <p>15 able to detect it because mostly what they were</p> <p>16 testing was bulk polypropylene or PROLENE in the</p> <p>17 interior of the -- of the fiber.</p> <p>18 And so in the human explant study, they</p> <p>19 did see degradation on the surface, but in this</p> <p>20 study, it was -- it just might have been a sampling</p> <p>21 problem as to why they couldn't see the loss in</p> <p>22 molecular weight that I would expect.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Is that your explanation? It's a</p>	<p>1 weight degradation?</p> <p>2 MR. BOWMAN: Object to form.</p> <p>3 THE WITNESS: You know, I do have some</p> <p>4 questions about the controls. You know, this --</p> <p>5 this control suture is, I don't think, the same as</p> <p>6 what was implanted.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. It's just not the same size in</p> <p>9 diameter; is that correct?</p> <p>10 A. Well, it's -- it's -- it's current</p> <p>11 PROLENE 40. And so is that what was implanted</p> <p>12 seven years prior? I -- I don't know the answer to</p> <p>13 that.</p> <p>14 Q. Did you make any effort to find out?</p> <p>15 A. I -- I couldn't tell. I mean --</p> <p>16 Q. And, Doctor, you'll agree that the</p> <p>17 control they used was PROLENE, correct?</p> <p>18 A. It was PROLENE.</p> <p>19 Q. And, Doctor, if -- what did you notice</p> <p>20 about mechanical properties of the sutures after</p> <p>21 seven years of implantation?</p> <p>22 A. They didn't see changes in the</p> <p>23 strength, but, again, it's -- it's -- strength is a</p> <p>24 volume average quantity averaged over the entire</p>

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<p>1 volume of the suture, where these changes are</p> <p>2 occurring at the surface.</p> <p>3 Q. In fact, Doctor, the physical</p> <p>4 properties -- or the mechanical properties, rather,</p> <p>5 of the sutures increased after seven years, didn't</p> <p>6 they?</p> <p>7 A. I mean, can you -- what are you looking</p> <p>8 at? I mean, can you -- I need to look at</p> <p>9 specific -- to answer that.</p> <p>10 Q. Did the -- well, did the mechanical</p> <p>11 properties of the sutures increase after seven</p> <p>12 years, Doctor?</p> <p>13 A. I need to look at the -- the data</p> <p>14 summary again. I need to look -- I need to refresh</p> <p>15 myself with the data before I answer that.</p> <p>16 So on page 11336182, there's the</p> <p>17 seven-year data summary that includes the straight</p> <p>18 strength, elongation and the modulus.</p> <p>19 Q. Just focus on my question.</p> <p>20 A. Well, I'm trying to answer it. I just</p> <p>21 need to look at the data.</p> <p>22 Q. You're just kind of reading aloud.</p> <p>23 Just why don't you look at the data, and then let's</p> <p>24 focus on my question.</p>	<p>1 Q. Okay. What about toughness? Is that a</p> <p>2 mechanical property?</p> <p>3 A. Well, it is, but it's not measured.</p> <p>4 Q. Okay.</p> <p>5 A. I mean, what's -- what's reported --</p> <p>6 Q. So --</p> <p>7 A. I'm going by what's reported, which is</p> <p>8 the breaking strength, the elongation and the</p> <p>9 Young's modulus. The breaking strength, as I said,</p> <p>10 is staying about the same. The elongation is</p> <p>11 getting longer and the modulus is going down.</p> <p>12 Q. Okay. So let's just make sure you and</p> <p>13 I are on the same page, Doctor.</p> <p>14 A. Okay.</p> <p>15 Q. If you can kind of just sit up and look</p> <p>16 at me.</p> <p>17 Breaking strength is a mechanical</p> <p>18 property, correct?</p> <p>19 A. It's a -- it's a -- it is a mechanical</p> <p>20 property.</p> <p>21 Q. Okay. Elongation -- elongation and</p> <p>22 Young's modulus are also mechanical properties,</p> <p>23 correct?</p> <p>24 A. That's right.</p>
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<p>1 A. Okay. I was trying to establish</p> <p>2 where... so the PROLENE showed -- looks like</p> <p>3 essentially not -- I mean, it's difficult to say</p> <p>4 because there's no standard deviations here. So</p> <p>5 what's significantly different -- I don't -- I</p> <p>6 don't see standard deviations. But the PROLENE</p> <p>7 sutures from zero to seven years, the changes in</p> <p>8 the strength are pretty small.</p> <p>9 Q. Okay. So, Doctor --</p> <p>10 MR. HUTCHINSON: So what was my</p> <p>11 question?</p> <p>12 THE WITNESS: Well, you said the --</p> <p>13 MR. HUTCHINSON: No. What's my</p> <p>14 question?</p> <p>15 (Whereupon the following question was</p> <p>16 read back by the reporter: Did the -- well, did</p> <p>17 the mechanical properties of the sutures increase</p> <p>18 after seven years, Doctor?)</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. That's my question.</p> <p>21 A. But "mechanical properties" is a broad</p> <p>22 term. Mechanical properties would include breaking</p> <p>23 strength, elongation, Young's modulus, that are</p> <p>24 listed here.</p>	<p>1 Q. All right. So if we look at the</p> <p>2 breaking strength of PROLENE, after seven years, it</p> <p>3 decreased 5 percent from baseline; is that right?</p> <p>4 A. That's the percentage that's shown.</p> <p>5 Right.</p> <p>6 Q. And elongation increased 111 percent;</p> <p>7 is that right?</p> <p>8 A. That's what it says.</p> <p>9 Q. Any reason to disagree with that,</p> <p>10 Doctor?</p> <p>11 A. That's what they measured. I mean,</p> <p>12 that's. . .</p> <p>13 Q. In fact, any reason to disagree with</p> <p>14 any of these numbers on page 183?</p> <p>15 A. I mean, that's what's reported in the</p> <p>16 study.</p> <p>17 Q. Okay. And you --</p> <p>18 A. So that's what I'm going by.</p> <p>19 Q. Right. And you have no reason to</p> <p>20 believe that these numbers are incorrect; is that</p> <p>21 right?</p> <p>22 A. Not -- I mean, not incorrectly</p> <p>23 measured. They --</p> <p>24 Q. And if we look at Young's modulus, the</p>

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<p>1 PROLENE decreased 70 percent; is that correct?</p> <p>2 A. That's right.</p> <p>3 Q. All right. And Young's modulus, that's</p> <p>4 just another word for stiffness; is that right?</p> <p>5 A. No. Stiffness is a different material</p> <p>6 property. Modulus is the initial slope</p> <p>7 approximately of the stress-strain curve. So it's</p> <p>8 a different property.</p> <p>9 Q. Right. And -- and, Doctor, what's your</p> <p>10 explanation for the increase -- mechanical -- or</p> <p>11 the improvement in the mechanical -- strike that.</p> <p>12 Doctor, what's your explanation for the</p> <p>13 improvement of the mechanical properties of the</p> <p>14 sutures from the seven-year dog study?</p> <p>15 A. I'm not sure why they're reporting this</p> <p>16 increase in elongation. I was looking mainly at</p> <p>17 the comments on degradation, oxidation. I'm not</p> <p>18 sure why they're reporting this increase in</p> <p>19 elongation at seven years.</p> <p>20 Q. Do you have an explanation?</p> <p>21 A. I just said I don't know why it's</p> <p>22 increasing at seven years.</p> <p>23 Q. All right. And, in fact, Doctor, you</p> <p>24 understood -- we talked about toughness earlier on;</p>	<p>1 Q. Yes, sir.</p> <p>2 A. Well, this is one point, right? So</p> <p>3 what's -- what you have here is initial slope,</p> <p>4 which would be the modulus, and then you've got a</p> <p>5 strength, which would be the -- the -- the endpoint</p> <p>6 of the test.</p> <p>7 Q. Okay. So if I understand correctly,</p> <p>8 what you would need is a stress-strain curve where</p> <p>9 breaking strength is the y-axis and elongation is</p> <p>10 the x-axis; is that right?</p> <p>11 A. No. The y-axis is the stress that's</p> <p>12 measured, and the x-axis is the strain --</p> <p>13 Q. Okay.</p> <p>14 A. -- or the elongation.</p> <p>15 Q. Okay.</p> <p>16 A. But it's not a -- what's reported here</p> <p>17 is the elongation at break, I believe --</p> <p>18 Q. And --</p> <p>19 A. -- strength at break.</p> <p>20 Q. And then what you would also need to</p> <p>21 look at is the area under the curve at time zero</p> <p>22 compared to the area under the curve at time -- at</p> <p>23 after year seven; is that right?</p> <p>24 A. No. Not really. I mean, it's -- it's</p>
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<p>1 is that correct?</p> <p>2 A. Yes.</p> <p>3 Q. Do you know if these sutures in the</p> <p>4 seven-year dog study became tougher after seven</p> <p>5 years of implantation?</p> <p>6 A. They didn't report it. I mean, the</p> <p>7 toughness is the slope under the stress-strain</p> <p>8 curve, but that's difficult to assess because the</p> <p>9 elongation is going up, but the stress is -- looks</p> <p>10 like it's going down. So I -- they didn't report</p> <p>11 that. So I -- I can't comment on that.</p> <p>12 Q. Okay. And -- but how would you -- what</p> <p>13 would you need to be able to comment on toughness?</p> <p>14 Would you need a stress-strain curve plotting this</p> <p>15 out?</p> <p>16 A. That's --</p> <p>17 MR. BOWMAN: Object to form.</p> <p>18 THE WITNESS: -- one way to measure the</p> <p>19 toughness, is the area under the stress-strain</p> <p>20 curve.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. Okay. And would you need any other</p> <p>23 data points on your stress-strain curve?</p> <p>24 A. Other data points on the curve?</p>	<p>1 a curve. So you can't -- oh -- okay. I think</p> <p>2 maybe I see what you're saying, look at the whole</p> <p>3 stress-strain curve measured at zero and then the</p> <p>4 whole curve measured --</p> <p>5 Q. Correct.</p> <p>6 A. -- at seven years.</p> <p>7 Q. That's correct.</p> <p>8 A. Yeah, I think that would give you the</p> <p>9 toughness.</p> <p>10 Q. Okay. And, in fact, if the area under</p> <p>11 the curve, after seven years, increased, that would</p> <p>12 mean the mechanical properties of the suture</p> <p>13 increased after seven years; is that right?</p> <p>14 A. No. It would mean that -- the</p> <p>15 toughness is measured -- approximated by the area</p> <p>16 under the curve was higher than if the area under</p> <p>17 the stress-strain curve is higher.</p> <p>18 Q. Okay. But we can assume that if the</p> <p>19 area under the curve, after seven years increased,</p> <p>20 then the sutures used in the dog study became</p> <p>21 tougher; we can agree to that?</p> <p>22 MR. BOWMAN: Object to form.</p> <p>23 THE WITNESS: I don't know. It's a</p> <p>24 strange finding. It's -- it's very surprising.</p>

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<p>1 It's not -- it's -- I -- I have a difficult time --</p> <p>2 that just doesn't usually happen. It's --</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. But -- but my question is can you and I</p> <p>5 agree that if the area under the curve, after seven</p> <p>6 years, increased, then toughness of the sutures</p> <p>7 increased after seven years in the dog study?</p> <p>8 A. I don't know. I'd have to look at the</p> <p>9 data without answering that question. I don't -- I</p> <p>10 need to see -- I need to see those curves and look</p> <p>11 at it. It just wasn't calculated here. So I don't</p> <p>12 want to make inferences from their data something</p> <p>13 that wasn't reported.</p> <p>14 Q. Okay.</p> <p>15 A. I mean. . .</p> <p>16 Q. So you would need to see a</p> <p>17 stress-strain curve?</p> <p>18 A. Well, I need to see all the</p> <p>19 calculations to form an opinion. I'm just going by</p> <p>20 what was provided. And this is a strange result,</p> <p>21 that it doesn't do anything for two years and all</p> <p>22 of a sudden you go to two to seven years, there's</p> <p>23 this increase in elongation. It's very surprising.</p> <p>24 You know, I need to see more analysis to make</p>	<p>1 Q. And my question is are these the same</p> <p>2 numbers that are used in the dog study?</p> <p>3 A. I -- I don't -- I -- this just</p> <p>4 doesn't -- I don't -- I need to think about this.</p> <p>5 MR. BOWMAN: Yeah. I'm having trouble,</p> <p>6 actually, figuring out what you're talking about as</p> <p>7 well. Is there -- is there somewhere you could</p> <p>8 point to where this data is taken from?</p> <p>9 THE WITNESS: I need to see the data in</p> <p>10 this report. I need to see -- this is break</p> <p>11 strength versus elongation. I need to see the full</p> <p>12 stress-strain curve that was measured for these</p> <p>13 materials. That's how toughness is -- in my</p> <p>14 understanding, it's the stress-strain curve. This</p> <p>15 is the break strength versus percent elongation. I</p> <p>16 need to see the raw data where these -- from the</p> <p>17 actual test, the stress-strain curve that's used to</p> <p>18 get the toughness. But I -- I can't comment on</p> <p>19 this. This is break strength versus elongation</p> <p>20 which is -- it's a different concept than what I</p> <p>21 think of in terms of what I've done in my work, in</p> <p>22 my papers where you plot the stress versus the</p> <p>23 strain, and you calculate the area under the curve</p> <p>24 is the toughness. I --</p>
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<p>1 conclusions about toughness and all those things.</p> <p>2 I mean, I just -- it's not in here, not in this</p> <p>3 document.</p> <p>4 MR. HUTCHINSON: Okay. Doctor, I'll</p> <p>5 hand you what we'll mark as Exhibit 8 to your</p> <p>6 deposition.</p> <p>7 (Whereupon Exhibit 8 was marked as an</p> <p>8 exhibit.)</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. This is a stress-strain curve where</p> <p>11 stress is the y-axis and strain is the x-axis. Do</p> <p>12 you see that?</p> <p>13 A. I do. But I have no idea where this</p> <p>14 came from. It's not in this document, and it's not</p> <p>15 in this report. And it's --</p> <p>16 Q. Well, stick with me on my questions for</p> <p>17 just a second. This shows toughness as -- under --</p> <p>18 as red at year zero using the same data points in</p> <p>19 the dog study; is that right?</p> <p>20 A. I don't know where this came from.</p> <p>21 This is --</p> <p>22 Q. I want you to compare it to the dog</p> <p>23 study.</p> <p>24 A. You just gave it --</p>	<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. In fact, Doctor, what we have here is</p> <p>3 breaking strength on the y-axis, correct?</p> <p>4 A. This is breaking strength. I'm --</p> <p>5 Q. All right. And then -- just stick with</p> <p>6 me and my questions and we'll get through this.</p> <p>7 We have elongation on the x-axis,</p> <p>8 correct?</p> <p>9 A. But elongation at what? Elongation at</p> <p>10 break? It just says "percent elongation."</p> <p>11 Q. And then, Doctor, my question to you is</p> <p>12 are these the same numbers on Exhibit 8 that are in</p> <p>13 the dog study for breaking strength and elongation?</p> <p>14 A. I -- I can't answer that question.</p> <p>15 It's --</p> <p>16 Q. Well --</p> <p>17 A. I can't pull numbers off of this graph</p> <p>18 and say that they're the same from this. I don't</p> <p>19 know where this came from. I mean, it's not</p> <p>20 plotted in the right way. It's not plotted as a --</p> <p>21 as a tensile strength versus strain. It's -- it's</p> <p>22 not plotted in a way that I'm accustomed -- so it's</p> <p>23 difficult to infer anything from this sort of</p> <p>24 analysis.</p>

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<p>1 Q. So, Doctor, at year zero, the breaking 2 strength of PROLENE was 1.68, correct? 3 A. Year zero, from the table it says 1.68. 4 Q. Right. And, in fact, Doctor, the 5 elongation at year seven was 1.6, correct? 6 A. Elongation at year seven? No. 7 Q. I'm sorry. The elongation at year -- 8 at time zero was 37; is that right? 9 A. That's the number in the table. But is 10 that elongation at break? I assume it is. That's 11 not the stress-strain curve. That's the terminal 12 point of the stress-strain curve. 13 Q. And, Doctor, stay with me. At year 14 seven, elongation is 78 percent; is that right? 15 A. That's what's listed in the table. 16 Q. And the table also lists at year seven 17 breaking strength at 1.6 pounds, correct? 18 A. That's the breaking strength. That's 19 the point at the end of the stress-strain curve and 20 my understanding the way they did this experiment. 21 Right? 22 Q. And the area under the curve at year 23 zero is smaller than the area under the curve at 24 year seven, isn't it?</p>	<p>1 A. I've not attempted to do it. They 2 report a strength. They report an elongation. They 3 report a modulus. There's this surprising increase 4 from year two to year seven, but -- 5 Q. And, Doctor, how would you create a 6 stress-strain curve to evaluate the toughness using 7 the information from the dog study? 8 MR. BOWMAN: Object to form. He just 9 testified that can't be done. 10 THE WITNESS: I can't make it from this 11 table. I would need to see the raw data. Maybe 12 it's in here. I don't know. I haven't -- I don't 13 know. 14 BY MR. HUTCHINSON: 15 Q. But have you looked for the raw data, 16 Doctor, that would support a stress-strain curve 17 analysis? 18 MR. BOWMAN: Object to form. Asked and 19 answered. 20 BY MR. HUTCHINSON: 21 Q. Have you looked for the data, Doctor? 22 A. I haven't looked for those data because 23 it's already shown in the table what I need to 24 know. There's a breaking strength. There's a</p>
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<p>1 A. I'm not -- I cannot answer that 2 question. This is not -- in order to answer, I -- 3 I -- I don't want to be difficult. But in order to 4 answer this toughness question, I need to see raw 5 data. These are -- these are -- these -- these 6 data are plotted at the end of the experiment. I 7 need to see the actual stress-strain curve. I need 8 to know the stress at 1 percent elongation, 5 9 percent elongation, 10 percent, until it breaks. 10 And from that stress-strain curve, you can do more 11 analysis. 12 But this is simply a plot of break 13 strength versus elongation at break. And I -- I 14 can't make those kinds of inferences that you're 15 trying to get me to agree to. 16 Q. Well, Doctor, are you -- have you 17 attempted, in any way, to create a toughness curve 18 to measure the PROLENE sutures from the dog study 19 at year zero and year seven? 20 MR. BOWMAN: Object to form. 21 THE WITNESS: As I said -- 22 BY MR. HUTCHINSON, 23 Q. I'm asking you, have you attempted to 24 do that?</p>	<p>1 elongation. There's a modulus. And so I -- I see 2 the elongation and the modulus data at break. 3 Q. In fact, Doctor, can you explain the 4 elongation increase of 111 percent at year seven? 5 Can you explain that? 6 MR. BOWMAN: Object to form. Asked and 7 answered. 8 THE WITNESS: Again, these are volume 9 -averaged tests. You're not looking at the changes 10 at the surface. My testimony has been about these 11 changes that happen at the surface, oxidation. The 12 degradation at the surface is confirmed in this 13 study. This is a volume-averaged mechanical 14 property, and I don't know how to interpret it 15 because it's volume averaged, and they're not 16 looking specifically at what's happening at the 17 surface. That's -- that's the same way I would 18 explain the molecular weight. 19 BY MR. HUTCHINSON: 20 Q. And, Doctor, do you know how to 21 interpret the finding of a decrease of 70 percent of 22 Young's modulus at year seven? 23 MR. BOWMAN: Object to form. 24 THE WITNESS: I'll answer that the way</p>

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<p>1 I just answered. It's like molecular weight. It's 2 a -- it's a bulk property measurement, volume 3 averaged across the fiber, and it doesn't tell you 4 about what's happening on the surface. It doesn't 5 tell you whether the surface is embrittled. All 6 it's telling you is about the bulk properties of 7 the fiber. It's the same as the molecular weight. 8 I think limited information can be gained from 9 this. 10 BY MR. HUTCHINSON: 11 Q. Doctor, how -- how can a PROLENE fiber 12 be embrittled if its elongation increases 111 13 percent? 14 A. PROLENE fibers were embrittled in those 15 human explants, and they scraped it off. It was 16 embrittled, oxidized polypropylene. It was in the 17 reports that it was embrittled, oxidized material 18 on the surface. And doing these volume-averaged 19 bulk tests is not going to tell you what's 20 happening at the surface. 21 Q. And, Doctor, does the data from the dog 22 study support your opinions about whether or not 23 PROLENE degrades? 24 A. It says in the report that they were</p>	<p>1 volume-averaged data that don't look at what's 2 happening at the surface. 3 BY MR. HUTCHINSON: 4 Q. Do they support your opinions, Doctor? 5 A. I don't think they inform my opinions 6 because it's a volume-averaged property. It 7 doesn't look at what's happening at the surface. 8 Q. You don't -- 9 MR. HUTCHINSON: Move to strike as 10 nonresponsive. 11 BY MR. HUTCHINSON: 12 Q. You don't think they inform your 13 opinions. My question, Doctor, is do the -- do the 14 data summary support -- not inform -- support your 15 opinions that degradation occurs in vivo with 16 PROLENE? Does this data support -- does this data 17 summary support your opinions? 18 A. Again, it doesn't -- I -- I don't know 19 what to do with these data. These are 20 volume-averaged properties. It doesn't tell you 21 what's happening at the surface. 22 Q. I'm not asking you what -- to do 23 anything with them. I'm asking you whether or not 24 this data summary supports your opinions that</p>
Page 187	Page 189
<p>1 going through -- I believe it says -- 2 Q. The data summary. I'm talking about 3 the data summary, Doctor. Stick with me. On page 4 193, the bottom -- 5 A. Well, you have to be a little more 6 specific. The mechanical property summary. 7 Q. Excuse me. Excuse me. 8 A. Yeah. 9 Q. Do the mechanical properties, shown on 10 page 183 of the seven-year dog study, support your 11 opinions that PROLENE degrades in vivo? 12 A. I -- I don't think they're relevant to 13 my opinions because they -- this is a 14 volume-averaged quantity, just like the molecular 15 weight. It's averaged over the entire volume of 16 the suture. So it doesn't tell you what's 17 happening at the surface, where the degradation is 18 occurring. 19 Q. Does the data summary support your 20 opinions about degradation in vivo, Doctor? 21 MR. BOWMAN: Object to form. Asked and 22 answered. 23 THE WITNESS: I don't think it can 24 inform my opinions because these are</p>	<p>1 PROLENE degrades in vivo? 2 MR. BOWMAN: Object to form. 3 THE WITNESS: It's -- 4 MR. BOWMAN: Asked and answered. 5 THE WITNESS: It's difficult to form an 6 opinion about it because they're not measuring the 7 right thing. They're measuring a volume-averaged 8 property, not what's happening at the surface. So 9 it's difficult to form an opinion. 10 MR. HUTCHINSON: Move to strike as 11 nonresponsive. 12 BY MR. HUTCHINSON: 13 Q. Doctor, does the data summary support 14 your opinions? 15 MR. BOWMAN: I'm instructing you not to 16 answer. 17 THE WITNESS: I'm not answering. I 18 don't -- I don't want to go back and forth anymore. 19 I believe I've answered it. 20 BY MR. HUTCHINSON: 21 Q. Doctor, I forgot to ask you one 22 question when we were talking about the nine 23 different products. Can you tell the jury what the 24 difference is between TVT EXACT and TVT and any</p>

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<p>1 other -- and in any of the other TVT products?</p> <p>2 MR. BOWMAN: Object to form.</p> <p>3 THE WITNESS: I don't remember the</p> <p>4 specific differences. There's differences in how</p> <p>5 the mesh can be cut, machine cut, laser cut.</p> <p>6 They're all made from the same mesh, which is what</p> <p>7 I was looking at in my report. They're all made</p> <p>8 from the same PROLENE, from the same -- from the</p> <p>9 same mesh, as I said earlier.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Doctor, is TVT ABBREVO laser cut or</p> <p>12 mechanically cut?</p> <p>13 MR. BOWMAN: Object to form.</p> <p>14 THE WITNESS: I can't remember. I</p> <p>15 believe it's laser cut. TVT's mechanically cut. I</p> <p>16 don't remember the details of it.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Doctor, do you know -- can you tell the</p> <p>19 jury whether or not TVT-O is mechanically cut or</p> <p>20 laser cut?</p> <p>21 A. I believe TVT-O is mechanically cut.</p> <p>22 Q. Doctor, are you aware of whether or not</p> <p>23 TVT-O is available in any type of other -- strike</p> <p>24 that.</p>	<p>1 A. PROSIMA is not a sling. It's a --</p> <p>2 Q. I'm not asking about the product. I'm</p> <p>3 asking about can you tell us how the mesh in</p> <p>4 PROSIMA is cut?</p> <p>5 A. I -- I don't remember. I wasn't</p> <p>6 stating opinions about the cutting of the mesh in</p> <p>7 my report.</p> <p>8 Q. Doctor, does the cutting of the mesh</p> <p>9 influence your opinions whatsoever regarding</p> <p>10 oxidizing PROLENE?</p> <p>11 MR. BOWMAN: Object to form.</p> <p>12 THE WITNESS: Well, the cutting of the</p> <p>13 mesh could affect the oxidation reaction.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Is that stated in your report marked as</p> <p>16 Exhibit 2, Doctor?</p> <p>17 A. I don't believe that's in my report.</p> <p>18 Q. Okay. Doctor, can you tell us how the</p> <p>19 mesh in GYNEMESH PS is cut?</p> <p>20 MR. BOWMAN: Object to form.</p> <p>21 THE WITNESS: I don't remember how that</p> <p>22 mesh is cut.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Can you tell us how the mesh in PROLIFT</p>
Page 191	Page 193
<p>1 Are you aware if TVT -- if TVT-O is</p> <p>2 available in laser cut mesh?</p> <p>3 A. I can't remember. Some of these</p> <p>4 products are offered as machine cut and laser cut.</p> <p>5 It's not always specified which the cut is.</p> <p>6 Sometimes it's difficult to figure out. But --</p> <p>7 Q. Is it your testimony, Doctor, it's not</p> <p>8 always specified in the product literature how the</p> <p>9 mesh is cut?</p> <p>10 A. I don't remember how the -- how the --</p> <p>11 the specifics of how the mesh is cut. Again, I was</p> <p>12 focusing on the specific PROLENE used in the mesh</p> <p>13 and its implantation in the body.</p> <p>14 Q. Doctor, can you tell us how the mesh in</p> <p>15 the TVT SECUR is cut?</p> <p>16 A. I believe that's a machine cut.</p> <p>17 Q. And can you tell us, Doctor, how the</p> <p>18 mesh in TVT EXACT is cut?</p> <p>19 MR. BOWMAN: Object to form.</p> <p>20 THE WITNESS: I don't remember about</p> <p>21 TVT EXACT.</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. Can you tell us how the mesh in PROSIMA</p> <p>24 is cut?</p>	<p>1 is cut?</p> <p>2 A. I don't remember how that mesh is cut.</p> <p>3 Q. Can you tell us how the mesh in</p> <p>4 PROLIFT+M is cut?</p> <p>5 A. I don't remember how that mesh is cut</p> <p>6 either.</p> <p>7 Q. Doctor, do you have any opinions</p> <p>8 whatsoever regarding how the mesh is cut as it</p> <p>9 relates to its reaction with tissue?</p> <p>10 MR. BOWMAN: Object to form.</p> <p>11 THE WITNESS: I mean, I thought I</p> <p>12 answered it. Those opinions are not in this</p> <p>13 report.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. And you're not offering any opinions</p> <p>16 about that in relation to the nine different</p> <p>17 products at issue here today, correct?</p> <p>18 A. I'm not offering any opinions about</p> <p>19 that.</p> <p>20 Q. Doctor, have --</p> <p>21 MR. BOWMAN: Counsel, I actually have</p> <p>22 that the three hours are up.</p> <p>23 MR. HUTCHINSON: Okay.</p> <p>24 BY MR. HUTCHINSON:</p>

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<p>1 Q. Doctor, do you intend to offer any</p> <p>2 opinions in this case that we've not already</p> <p>3 discussed?</p> <p>4 A. No.</p> <p>5 Q. Do you plan on supplementing your</p> <p>6 opinions?</p> <p>7 A. I don't know.</p> <p>8 Q. Okay. Have you understood all of my</p> <p>9 questions so far?</p> <p>10 A. Mostly.</p> <p>11 Q. Is there a question that's lingering in</p> <p>12 your mind that you don't understand that I need to</p> <p>13 reask?</p> <p>14 MR. BOWMAN: I did instruct him not to</p> <p>15 answer at least two questions.</p> <p>16 THE WITNESS: No.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Doctor, is there anything about the</p> <p>19 testimony you've given today that you would like to</p> <p>20 change?</p> <p>21 A. No.</p> <p>22 Q. Do you feel good about how you did</p> <p>23 today as an expert witness?</p> <p>24 MR. BOWMAN: Object to form.</p>	<p>1 CERTIFICATE</p> <p>2 STATE OF TENNESSEE)</p> <p>3 COUNTY OF DAVIDSON)</p> <p>4 I, Lise S. Matthews, RMR, CRR, CCP, LCR</p> <p>5 353, Licensed Court Reporter and Notary Public, in</p> <p>6 and for the State of Tennessee, do hereby certify</p> <p>7 that the above deposition was reported by me, and</p> <p>8 the transcript is a true and accurate record to the</p> <p>9 best of my knowledge, skills, and ability.</p> <p>10 I further certify that I am not related</p> <p>11 to nor an employee of counsel or any of the parties</p> <p>12 to the action, nor am I in any way financially</p> <p>13 interested in the outcome of this case.</p> <p>14 I further certify that I am duly</p> <p>15 licensed by the Tennessee Board of Court Reporting</p> <p>16 as a Licensed Court Reporter as evidenced by the</p> <p>17 LCR number and expiration date following my name</p> <p>18 below. I further certify that this transcript is</p> <p>19 the work product of this court reporting agency and</p> <p>20 any unauthorized reproduction and/or transfer of it</p> <p>21 will be in violation of Tennessee Code Annotated</p> <p>22 39-14-104, Theft of Services.</p> <p>23 IN WITNESS WHEREOF, I have hereunto set</p> <p>24 my hand and affixed my notarial seal this _____</p> <p>day of _____, 2016.</p> <p>Lise S. Matthews, RMR, CRR, CRC</p> <p>LCR 353 Expiration Date 6/30/2016</p> <p>Notary Public Commission Expires</p> <p>March 6, 2018</p>
<p>Page 195</p> <p>1 THE WITNESS: I don't know. Our three</p> <p>2 hours is up. I think we're done.</p> <p>3 MR. HUTCHINSON: Thank you.</p> <p>4 Counsel, before we go -- we go off the</p> <p>5 record, just to make a housekeeping note, counsel</p> <p>6 has given me a flash drive that contains what?</p> <p>7 MR. BOWMAN: Reliance materials, pretty</p> <p>8 much everything that was reviewed or referenced in</p> <p>9 the report.</p> <p>10 MR. HUTCHINSON: Okay.</p> <p>11 (Proceedings concluded at 12:17 p.m.)</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	

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EXHIBIT G

Jimmy W. Mays, Ph.D.

Page 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC
REPAIR SYSTEM PRODUCTS
LIABILITY LITIGATION

Master File No.
2:12-MD-02327

MDL NO. 2327

THIS DOCUMENT RELATES TO THE
FOLLOWING CASES IN WAVE 1 OF MDL
200:

JOSEPH R. GOODWIN
US DISTRICT JUDGE

Bonnie Blake, et al., v. Ethicon,
Inc., et al.,
Civil Action No. 2:12-cv-00995

Robin Bridges v. Ethicon, Inc.,
et al.,
Civil Action No. 2:12-cv-00651

Carey Beth Cole, et al., v.
Ethicon, Inc., et al.,
Civil Action No. 2:12-cv-00483

(Continued on next page)

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MARCH 2, 2016

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Deposition of JIMMY W. MAYS, PhD, held at
Marco Island Marriott Beach Resort, South Collier
Boulevard, Marco Island, Florida, commencing
at 8:36 a.m., on the above date, before Joan L.
Pitt, Registered Merit Reporter, Certified
Realtime Reporter, and Florida Professional
Reporter.

- - -

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Jimmy W. Mays, Ph.D.

Page 2	Page 4
<p>1 Angela Coleman, et al., v. Ethicon, Inc., et al., 2 Civil Action No. 2:12-cv-01267 3 Dina Destefano-Raston, et al., v. Ethicon, Inc., et al., 4 Civil Action No. 2:12-cv-01169 5 Dennis W. Dixon re: Estate of Virginia M. Dixon, Deceased 6 v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-01081 7 8 Karyn E. Drake, et al., v. Ethicon, Inc., et al., 9 Civil Action No. 2:12-cv-00747 10 11 Paula Fisk v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-00848 12 Pamela Free v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-00423 13 14 Teresa Georgilakis et al., v. Ethicon, Inc., et al., 15 Civil Action No. 2:12-cv-00829 16 17 Louise Grabowski v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-00683 18 Dawna Hankins v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-00369 19 20 Nancy Hooper et al., v. Ethicon, Inc., et al., 21 Civil Action No. 2:12-cv-00493 22 23 Alfreda Lee, et al., v. Ethicon, Inc., et al., 24 Civil Action No. 2:12-cv-01013 25 26 Deborah Lozano, et al., v. Ethicon, Inc., et al., 27 Civil Action No. 2:12-cv-00347 28 29 (Continued on next page) 30</p>	<p>1 APPEARANCES: 2 DOUGLAS C. MONSOUR, ESQUIRE Monsour Law Firm 3 404 North Green Street Longview, Texas 75601 4 903.758.5757 doug@monsourlawfirm.com 5 Representing Plaintiffs 6 JIM M. PERDUE JR., ESQUIRE Perdue and Kidd 7 510 Bering Drive, Suite 500 Houston, Texas 77057 8 713.520.2500 jperduejr@perdueandkidd.com 9 Representing Plaintiffs 10 11 CHAD R. HUTCHINSON, ESQUIRE Butler Snow LLP 12 1020 Highland Colony Parkway, Suite 1400 Ridgeland, Mississippi 39157 601.985.4401 13 chad.hutchinson@butlersnow.com Representing Defendants 14 15 16 17 18 19 20 21 22 23 24</p>
Page 3	Page 5
<p>1 Charlene Miracle v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-00510 2 3 Noemi Padilla v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-00567 4 Jennifer Reyes, et al., v. Ethicon, Inc., et al., 5 Civil Action No. 2:12-cv-05664 6 Jennifer Sikes v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-00501 7 8 Carrie Smith v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-00258 9 Isabel Swint, et al., v. Ethicon, Inc., et al., 10 Civil Action No. 2:12-cv-00786 11 Krystal Teasley, v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-00500 12 13 Susan Thaman v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-00279 14 Kimberly Thomas v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-00499 15 16 Barbara J. Vignos-Ware, et al., v. Ethicon, Inc., et al., 17 Civil Action No. 2:12-cv-00761 18 19 Cathy Warlick v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-00276 20 Elizabeth Blynn Wilson Wolfe v. Ethicon, Inc., et al., 21 Civil Action No. 2:12-cv-001286 22 Julie Wroble, et al., v. Ethicon, Inc., et al., 23 Civil Action No. 2:12-cv-00883 24</p>	<p>1 --- 2 I N D E X 3 --- 4 Testimony of: JIMMY W. MAYS, PhD 5 6 DIRECT EXAMINATION BY MR. HUTCHINSON 6 7 8 9 E X H I B I T I N D E X 10 11 MAYS DESCRIPTION PAGE 12 No. 1 NOTICE TO TAKE DEPOSITION OF JIMMY MAYS 6 13 No. 2 FILE MATERIALS 7 14 No. 3 RULE 26 EXPERT REPORT OF JIMMY W. MAYS 12 15 No. 4 MEMO RE: PROLENE MICROCRACKING DATED 110 NOVEMBER 5, 1984 16 ETH.MESH.15958452 - ETH.MESH.15958469 17 No. 5 ARTICLE - IN VIVO OXIDATIVE DEGRADATION 129 OF POLYPROPYLENE PELVIS MESH, IMEL, ET 18 AL., BIOMATERIALS 73 (2-15) 131-141, ACCEPTED SEPTEMBER 9, 2015 19 20 No. 6 SEVEN YEAR DOG STUDY 148 21 22 No. 7 TABLE - BREAK STRENGTH (LBS.) AND % 159 ELONGATION 23 24</p>

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Jimmy W. Mays, Ph.D.

<p style="text-align: right;">Page 6</p> <p>1 - - -</p> <p>2 THE COURT REPORTER: Raise your right hand,</p> <p>3 please. Do you swear or affirm the testimony you</p> <p>4 give will be the truth, the whole truth, and nothing</p> <p>5 but the truth?</p> <p>6 THE WITNESS: Yes.</p> <p>7 THE COURT REPORTER: Thank you.</p> <p>8 JIMMY W. MAYS, PhD, called as a witness by the</p> <p>9 Defendants, having been first duly sworn, testified</p> <p>10 as follows:</p> <p>11 DIRECT EXAMINATION</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. Good morning.</p> <p>14 A. Good morning.</p> <p>15 Q. My name is Chad Hutchinson. I'm counsel for</p> <p>16 Ethicon and Johnson & Johnson.</p> <p>17 Dr. Mays, you understand you're under oath?</p> <p>18 A. I do.</p> <p>19 Q. And do you understand you're giving testimony</p> <p>20 subject to the penalty of perjury?</p> <p>21 A. Yes.</p> <p>22 (Mays Exhibit No. 1 was marked for</p> <p>23 identification.)</p> <p>24</p>	<p style="text-align: right;">Page 8</p> <p>1 Q. When you say it's not everything you've seen,</p> <p>2 what do you mean by that?</p> <p>3 A. Well, I've got a whole electronic file of</p> <p>4 documents that I've gone through.</p> <p>5 Q. Why did you choose to bring the documents in</p> <p>6 Exhibit 2 today rather than the documents that you have</p> <p>7 on the electronic file?</p> <p>8 A. I thought those were the most relevant to the</p> <p>9 matter at hand.</p> <p>10 Q. Okay. I see 49 hours on the invoice. Does</p> <p>11 that represent the total amount of time that you've</p> <p>12 spent on the Ethicon litigation?</p> <p>13 A. No, that was as of the time I submitted that</p> <p>14 bill, which I think was late December or maybe early</p> <p>15 January.</p> <p>16 Q. Okay. And so up until the time when you were</p> <p>17 first retained, up until January 4, 2016, you spent 49.5</p> <p>18 hours; correct?</p> <p>19 A. Correct.</p> <p>20 Q. All right. And since January 4, 2016, up until</p> <p>21 today, March 2, how many hours have you spent?</p> <p>22 A. Probably about 20.</p> <p>23 Q. So that's approximately 70 hours total that</p> <p>24 you've spent?</p>
<p style="text-align: right;">Page 7</p> <p>1 BY MR. HUTCHINSON:</p> <p>2 Q. I've handed you what's been marked as Exhibit 1</p> <p>3 to your deposition. Have you seen that document before?</p> <p>4 A. Yes.</p> <p>5 Q. And that's a notice of deposition; correct?</p> <p>6 A. Correct.</p> <p>7 Q. And that notice lists all the cases in which</p> <p>8 you're designated as an expert witness in this -- in</p> <p>9 this litigation; correct?</p> <p>10 A. As far as I know, yes.</p> <p>11 Q. And you brought with you some documents today?</p> <p>12 A. I did.</p> <p>13 Q. And you're handing those documents to me. It's</p> <p>14 a file approximately 2 inches thick in a manila folder.</p> <p>15 We'll mark it as Exhibit 2 to your deposition.</p> <p>16 (Mays Exhibit No. 2 was marked for</p> <p>17 identification.)</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. What does this include?</p> <p>20 A. It's got the bill that I've submitted thus far</p> <p>21 in this case and also the papers and documents that I've</p> <p>22 reviewed in preparing for the depo today; not everything</p> <p>23 I've seen, but everything I basically reviewed for</p> <p>24 today.</p>	<p style="text-align: right;">Page 9</p> <p>1 A. Yes.</p> <p>2 Q. Thank you. And do you still charge \$300 an</p> <p>3 hour for review and \$500 an hour for testimony?</p> <p>4 A. Correct.</p> <p>5 Q. Doctor, you've been an expert witness before;</p> <p>6 is that correct?</p> <p>7 A. Yes.</p> <p>8 Q. And you've been deposed at least twice as an</p> <p>9 expert against Boston Scientific?</p> <p>10 A. Yes.</p> <p>11 Q. And you read those transcripts?</p> <p>12 A. Yes. It's been a while, but I've read them.</p> <p>13 Q. And you stand by the testimony that you've</p> <p>14 given?</p> <p>15 A. I do.</p> <p>16 Q. What's your area of expertise?</p> <p>17 A. I'm a polymer scientist.</p> <p>18 Q. Do you have a specialty as a polymer scientist?</p> <p>19 A. Well, I've been involved with polymers broadly.</p> <p>20 I've worked in the industry for a while. I've been at</p> <p>21 the university since 1988. I've got an affiliation with</p> <p>22 Oak Ridge National Lab. So I've worked broadly in the</p> <p>23 area of polymer science, including polypropylene.</p> <p>24 Q. Do you have a specialty, sir?</p>

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<p style="text-align: right;">Page 10</p> <p>1 A. I would say my specialty is two things, polymer 2 synthesis and polymer characterization. 3 Q. You don't have a specialty in organic coatings, 4 do you? 5 A. No. 6 Q. Doctor, all the work that you've done in mesh 7 litigation has been for the plaintiffs; is that correct? 8 A. Yes. 9 Q. And you've been retained to offer opinions 10 against Boston Scientific? 11 A. Yes. 12 Q. And Ethicon? 13 A. Yes. 14 Q. What about AMS? 15 A. No. 16 Q. Bard? 17 A. No. 18 Q. Any other mesh manufacturers? 19 A. No. 20 Q. Any other polypropylene manufacturers? 21 A. Actually, I have been involved with litigation 22 involving polyolefins, including polypropylene, at one 23 point in time, but this was years ago. 24 Q. Was that a patent matter?</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. In what matters? 2 A. It was the same thing, Boston Scientific. 3 (Mays Exhibit No. 3 was marked for 4 identification.) 5 BY MR. HUTCHINSON: 6 Q. Doctor, I'll hand you what we'll mark as 7 Exhibit 3 to your deposition. That's a copy of your 8 expert report; correct? 9 A. Yes. 10 Q. And is it complete? 11 A. That's what I'm looking at. 12 It looks to be complete. 13 Q. Is it accurate? 14 A. Yes. 15 Q. Are you aware of any errors? 16 A. I caught a couple of typos, but they were just, 17 you know, nonconsequential-type things. 18 Q. Doctor, how many hours did you spend preparing 19 that report? 20 A. I could go back and review my bill and tell you 21 exactly, but it was something of the order of probably 22 30 hours actually preparing the report. 23 Q. Okay. So if we look at that bill that has 49 24 hours, that would be 30 hours preparing your report and</p>
<p style="text-align: right;">Page 11</p> <p>1 A. It was a patent matter. 2 Q. When were you first contacted in this Ethicon 3 mesh litigation? 4 A. In this litigation, it was sometime in the fall 5 of last year. 6 Q. The fall of 2015? 7 A. Yes. 8 Q. And who contacted you? 9 A. I think it was Mr. Perdue initially. 10 Q. And what were you asked to do? 11 A. I was basically asked if I might be available 12 to work with them on this matter. 13 Q. And what did you tell them? 14 A. I said, "Yeah, I think I have time and can do 15 it." 16 Q. Did you ask any questions about the scope of 17 the engagement? 18 A. I really didn't, as I recall. 19 Q. Have you ever worked with Mr. Perdue before? 20 A. We worked together in the Boston Scientific 21 matter. 22 Q. What about Mr. Monsour? Have you ever worked 23 with him before? 24 A. Yes.</p>	<p style="text-align: right;">Page 13</p> <p>1 19 hours reviewing documents and literature; correct? 2 A. Roughly that, yeah. 3 Q. Okay. Thank you. 4 Did you draft that report, sir? 5 A. I did. 6 Q. Did you have any assistance in drafting that 7 report? 8 A. No, I pecked it out with two fingers on my -- 9 on my laptop. 10 Q. Did anybody have access to that document, sir, 11 during the drafting stage? 12 A. I did send it at the point when it was a full 13 draft, with references included, at that point I did 14 send it to the attorneys to have a look. 15 Q. Okay. But that expert report is your work and 16 your work only; correct? 17 A. Correct. 18 Q. And does that report contain all the opinions 19 that you intend to offer in this case? 20 A. Well, I can't say that with absolute certainty. 21 It might depend on what you ask me, but the gist of what 22 I plan to testify about is in this report. 23 Q. Okay. But when you began preparing that 24 report, did you intend to include all the opinions that</p>

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<p style="text-align: right;">Page 14</p> <p>1 you intend to assert against Ethicon and Johnson & 2 Johnson in this litigation? 3 A. That was my intent, yes. 4 Q. Doctor, did you review or rely on any documents 5 or literature other than what's contained in your 6 reliance list? 7 A. As I mentioned, I certainly read a lot of 8 literature in preparing for this. I've worked in the 9 area of polypropylene for years, and things I've been 10 exposed to 30 years ago, I still rely on some of that 11 knowledge. Right? But basically what I relied on is in 12 the references listed at the end of this report. 13 Q. A copy of your CV is included within that 14 report; correct? 15 A. Correct. 16 Q. And is that the most recent version of your CV? 17 A. It changes often as new papers are published 18 and new presentations are made. Let me take a look at 19 it and I can tell you how up-to-date it is. 20 This one is about a month old, so it's quite 21 up-to-date, but not perfect. 22 Q. What would make it perfect? 23 A. A couple of additional papers that were 24 submitted at the time have been accepted, and maybe one</p>	<p style="text-align: right;">Page 16</p> <p>1 MR. MONSOUR: Objection. Form. Would you just 2 state those out for me? 3 Q. Stress urinary incontinence or pelvic organ 4 prolapse. 5 A. No. 6 Q. Doctor, have you ever published any articles on 7 Prolene? 8 A. I can't say with certainty that I haven't, 9 because I've been in the game a while. I worked for 10 Hercules, one of the largest polypropylene producers in 11 the world at that time, for five years, but I don't 12 explicitly recall anything. 13 Q. Okay. And my question is specifically about 14 Prolene. 15 A. I understand. 16 Q. Okay. Doctor, have you ever given any 17 presentations regarding Prolene? 18 A. Again I'll say the same thing I just said 19 regarding the publication. I've been in the area a long 20 time, I've worked with polypropylene before, but I don't 21 recall anything explicitly with Prolene. 22 Q. Thank you. Doctor, is all your research 23 experience included on your CV? 24 A. Yes, I think it's a good representation of my</p>
<p style="text-align: right;">Page 15</p> <p>1 additional paper that's been submitted for publication. 2 Q. What papers? 3 A. Again, I'd have to go back and look. 4 Q. Do the papers have anything to do with 5 polypropylene? 6 A. They don't. 7 Q. Anything to do with pelvic mesh? 8 A. No. 9 Q. Doctor, are you currently working on any 10 articles that you intend to submit for publication? 11 A. Yes. I'm continually working on articles that 12 I plan to submit for publication. 13 Q. Do they have anything to do with Prolene? 14 A. No. 15 Q. Pelvic mesh? 16 A. No. 17 Q. Doctor, Imel was the first publication where 18 you discussed pelvic mesh products; correct? 19 A. Correct. 20 Q. And you didn't do the hands-on testing on those 21 explants referenced in the Imel paper, did you? 22 A. I did not. 23 Q. Have you ever published anything regarding SUI 24 or POP?</p>	<p style="text-align: right;">Page 17</p> <p>1 research experience. 2 Q. Have you ever done any research regarding 3 Prolene? 4 A. You mean laboratory experiments? 5 Q. Yes, sir. 6 A. No laboratory experiments. Literature 7 research, yes. 8 Q. And, Doctor, since 2014 when you were deposed 9 in the Boston Scientific litigation, have you ever 10 worked with a medical device company specifically 11 regarding pelvic mesh products? 12 A. I'm sorry. Could you repeat that? 13 Q. Sure. Since 2014, have you ever worked with a 14 medical device company regarding pelvic mesh products? 15 A. No. 16 Q. And, Doctor, before litigation against Boston 17 Scientific, had the focus of your research interests 18 been on pelvic mesh? 19 A. No. 20 Q. Doctor, have you ever talked with any of the 21 plaintiffs in this litigation? 22 A. No. 23 Q. Have you ever talked with any of the 24 plaintiffs' family members or friends in this</p>

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<p style="text-align: right;">Page 18</p> <p>1 litigation?</p> <p>2 A. Not to my knowledge.</p> <p>3 Q. What about any of the doctors?</p> <p>4 A. No.</p> <p>5 Q. Other than attorneys, have you discussed your</p> <p>6 opinions with anyone else?</p> <p>7 A. No.</p> <p>8 Q. None of your colleagues?</p> <p>9 A. No.</p> <p>10 Q. Any type of scientific organization?</p> <p>11 A. No.</p> <p>12 Q. Doctor, did you sign a confidentiality</p> <p>13 agreement with respect to the documents you reviewed for</p> <p>14 Ethicon?</p> <p>15 A. Yes.</p> <p>16 Q. Where is that?</p> <p>17 A. I don't know.</p> <p>18 Q. Would it be at your house, or your office,</p> <p>19 rather?</p> <p>20 A. It probably would be in my office in Knoxville.</p> <p>21 Q. Do you advertise your services?</p> <p>22 A. I do not.</p> <p>23 Q. Would the time sheet that we have in the</p> <p>24 collective Exhibit No. 2 reflect all the time that you</p>	<p style="text-align: right;">Page 20</p> <p>1 Q. Are you an expert in female anatomy?</p> <p>2 A. No.</p> <p>3 Q. Doctor, based on your review of the documents,</p> <p>4 you'll agree that Ethicon performed biocompatibility</p> <p>5 testing on its Prolene?</p> <p>6 A. Yes.</p> <p>7 Q. And do you have any opinions whatsoever</p> <p>8 regarding the biocompatibility testing of Prolene?</p> <p>9 A. I've already said I'm not an expert in</p> <p>10 biocompatibility, but it seemed to be standard-type</p> <p>11 biocompatibility testing.</p> <p>12 Q. And based upon your review, do you believe that</p> <p>13 Ethicon appropriately did its biocompatibility testing?</p> <p>14 A. I -- as far as I can tell, they did. What they</p> <p>15 didn't do that I think they should have done is actually</p> <p>16 performed clinical trials with the material in the</p> <p>17 application in which it was intended.</p> <p>18 Q. Doctor, have you ever designed or participated</p> <p>19 in a clinical trial regarding mesh?</p> <p>20 A. Not regarding mesh.</p> <p>21 Q. Have you ever designed or participated in any</p> <p>22 type of clinical trial regarding Prolene?</p> <p>23 A. No.</p> <p>24 Q. Have you ever been involved in any clinical</p>
<p style="text-align: right;">Page 19</p> <p>1 spent in this litigation for Ethicon?</p> <p>2 A. This reflects the time I spent in this</p> <p>3 litigation as of January 4 of this year.</p> <p>4 Q. All right. Thank you.</p> <p>5 Doctor, do you anticipate doing any additional</p> <p>6 work or research in this Ethicon litigation?</p> <p>7 A. I'm not sure.</p> <p>8 Q. You don't have any plans to, sitting right</p> <p>9 here, sitting here today?</p> <p>10 A. Not as I sit here.</p> <p>11 Q. Have you asked counsel for any information or</p> <p>12 documents that you've not received yet that you believe</p> <p>13 may be helpful?</p> <p>14 A. No.</p> <p>15 Q. I believe it's your testimony you're not an</p> <p>16 expert in biomaterials?</p> <p>17 A. Well, I have worked in the area of</p> <p>18 biomaterials. I have considerable expertise in</p> <p>19 polymeric biomaterials.</p> <p>20 Q. You are holding yourself out as an expert in</p> <p>21 biomaterials; is that correct?</p> <p>22 A. Yes.</p> <p>23 Q. Are you an expert in biocompatibility?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 21</p> <p>1 research regarding mesh?</p> <p>2 A. No.</p> <p>3 Q. Have you ever received any grants for studying</p> <p>4 mesh in your positions at UT or UAB?</p> <p>5 A. No.</p> <p>6 Q. Have you ever designed pelvic mesh?</p> <p>7 A. No.</p> <p>8 Q. And you've never done any biomechanical testing</p> <p>9 of pelvic mesh; correct?</p> <p>10 A. Correct.</p> <p>11 Q. Have you ever personally inspected a mesh</p> <p>12 explant of any kind?</p> <p>13 A. Yes.</p> <p>14 Q. Would that be for the 11 explants in the Boston</p> <p>15 Scientific litigation?</p> <p>16 A. Yes.</p> <p>17 Q. Anything else?</p> <p>18 A. Concerning polypropylene mesh?</p> <p>19 Q. Correct.</p> <p>20 A. I've certainly looked at literature that</p> <p>21 describes it.</p> <p>22 Q. I'm talking about actually inspecting an actual</p> <p>23 explant specimen.</p> <p>24 A. No, not other than those Boston Scientific</p>

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<p style="text-align: right;">Page 22</p> <p>1 materials.</p> <p>2 Q. And you've never personally inspected a mesh</p> <p>3 explant of Prolene, have you?</p> <p>4 A. No.</p> <p>5 Q. Have you ever done any testing of a mesh</p> <p>6 explant of Prolene?</p> <p>7 A. Not of Prolene.</p> <p>8 Q. And, Doctor, are you -- do you know what</p> <p>9 medical products you're here and designated to testify</p> <p>10 about and give opinions about?</p> <p>11 A. Yes, I do. They're listed at the beginning of</p> <p>12 my report.</p> <p>13 Q. Where do you see that?</p> <p>14 A. If you go over on page 4, under background, the</p> <p>15 various Prolene mesh products are listed there.</p> <p>16 Q. Sir, do you know if all those products -- and</p> <p>17 just for the record, we're looking at Prolene Mesh,</p> <p>18 Gynemesh PS, Prolift, Prolift +M, Prosima, TVT-Secur --</p> <p>19 I'm sorry -- Gynecare TVT System, TVT Retropubic, TVT-O,</p> <p>20 TVT-Abbrevio, TVT-Secur, and TVT-Exact; is that correct?</p> <p>21 A. I'm sorry. Could you --</p> <p>22 Q. Is that the list of the medical --</p> <p>23 A. That is the list, yes.</p> <p>24 Q. And, Doctor, do you know if all those products</p>	<p style="text-align: right;">Page 24</p> <p>1 Q. Doctor, what about TVT-Secur, the mesh in</p> <p>2 TVT-Secur? Strike that.</p> <p>3 Prosima. Doctor, do you know what other</p> <p>4 materials other than Prolene are in the mesh material in</p> <p>5 Prosima?</p> <p>6 A. Not as I sit here.</p> <p>7 Q. Doctor, have you ever seen -- and when I say</p> <p>8 "these medical devices," just so you and I are</p> <p>9 communicating, I'm talking about the medical devices</p> <p>10 that you're here to give testimony about. Are we</p> <p>11 communicating?</p> <p>12 A. Yes, sir.</p> <p>13 Q. Okay. Doctor, have you ever seen these medical</p> <p>14 devices?</p> <p>15 A. No.</p> <p>16 Q. Have you ever held them in your hands?</p> <p>17 A. No. I've seen pictures, but that's as far as</p> <p>18 it goes.</p> <p>19 Q. Doctor, have you ever held a piece of Prolene</p> <p>20 in your hand?</p> <p>21 A. I very well could have with my years of</p> <p>22 experience in polymer science. Just as an example, our</p> <p>23 polymer characterization lab at the University of</p> <p>24 Tennessee, we perform a lot of outside analyses for</p>
<p style="text-align: right;">Page 23</p> <p>1 are made up of 100 percent Prolene?</p> <p>2 A. It's my understanding that those materials are</p> <p>3 made of Prolene, yes.</p> <p>4 Q. And 100 percent of Prolene?</p> <p>5 A. Well, Prolene is a formulation, so there's</p> <p>6 additives in there. It's polypropylene plus appropriate</p> <p>7 additives.</p> <p>8 Q. But my question, sir, is it your testimony that</p> <p>9 these products are made of 100 percent Prolene?</p> <p>10 A. Well, the mesh is in there, but there's also a</p> <p>11 delivery device and packaging, so there are things other</p> <p>12 than Prolene, but the mesh itself is Prolene.</p> <p>13 Q. Okay. So, Doctor, is it your testimony that</p> <p>14 the Prolift +M is made of 100 percent Prolene?</p> <p>15 A. No. There could well be other things in some</p> <p>16 of these materials, yes.</p> <p>17 Q. In the mesh?</p> <p>18 A. There could be biodegradable material, for</p> <p>19 example.</p> <p>20 Q. Okay. What other material other than Prolene</p> <p>21 does Prolift +M consist of in the mesh?</p> <p>22 A. I'd have to go back and review that.</p> <p>23 Q. You don't know today?</p> <p>24 A. As I sit here, I can't say.</p>	<p style="text-align: right;">Page 25</p> <p>1 companies, for individuals, and it's certainly possible</p> <p>2 that some passed through at some time.</p> <p>3 Q. Doctor, sitting here today, can you ever recall</p> <p>4 an instance where you've held a piece of Prolene in your</p> <p>5 hand?</p> <p>6 A. No.</p> <p>7 Q. And, Doctor, have you ever done any hands-on</p> <p>8 testing of Prolene?</p> <p>9 A. No.</p> <p>10 Q. Doctor, when is -- I want to go back to these</p> <p>11 products, if you will, okay?</p> <p>12 A. Okay.</p> <p>13 Q. When's the first time you've ever heard of</p> <p>14 these products?</p> <p>15 A. I've certainly heard of Prolene, having been in</p> <p>16 the polypropylene game for a long time, but these</p> <p>17 particular mesh products, I knew pelvic mesh was out</p> <p>18 there, I may have heard the names, but they certainly</p> <p>19 didn't stick.</p> <p>20 Q. When was the first time that you'd heard the</p> <p>21 name of these products, sir?</p> <p>22 A. I would say, these products, at the time I got</p> <p>23 involved in this litigation.</p> <p>24 Q. And that would have been in the fall of 2005?</p>

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<p style="text-align: right;">Page 26</p> <p>1 A. 2015.</p> <p>2 Q. Thank you, sir. I like it when a scientist is</p> <p>3 accurate.</p> <p>4 Doctor, do you have any idea what the</p> <p>5 indications are for these products?</p> <p>6 A. You mean the medical indications?</p> <p>7 Q. Yes, sir.</p> <p>8 A. Well, stress urinary incontinence, pelvic organ</p> <p>9 prolapse.</p> <p>10 Q. Do you know how long these products have been</p> <p>11 on the market?</p> <p>12 A. The exact date for these individual products, I</p> <p>13 don't.</p> <p>14 Q. Do you know the physical dimensions of the mesh</p> <p>15 in these individual products?</p> <p>16 A. No.</p> <p>17 Q. And, Doctor, do you know the weight of the mesh</p> <p>18 in these individual products?</p> <p>19 A. No, not as I sit here.</p> <p>20 Q. Doctor, do you know a woman's lifetime risk of</p> <p>21 developing SUI or POP?</p> <p>22 A. I don't.</p> <p>23 Q. Do you know the natural progression of the</p> <p>24 disease?</p>	<p style="text-align: right;">Page 28</p> <p>1 process Ethicon uses to make Prolene?</p> <p>2 A. Well, I know how the polypropylene is produced</p> <p>3 and I know that the material is thin-mixed with various</p> <p>4 additives, processing aids, antioxidants.</p> <p>5 Q. Anything else?</p> <p>6 A. Then it's extruded. Fibers are produced by</p> <p>7 passing through a spinneret. Those fibers then get</p> <p>8 woven into a mesh product.</p> <p>9 Q. Do you know at what temperature?</p> <p>10 A. The exact temperature of the extrusion, it</p> <p>11 would have to be well above the melting temperature of</p> <p>12 the polypropylene, which is 165 degrees C, so it's</p> <p>13 something of the order of 200 degrees C.</p> <p>14 Q. Do you know where Prolene is made?</p> <p>15 A. The documentation I've seen leads me to believe</p> <p>16 that it's made in Pennsylvania somewhere, near</p> <p>17 Philadelphia.</p> <p>18 Q. And, Doctor, is the mesh that's contained in</p> <p>19 these individual products, is it woven or knitted?</p> <p>20 A. It's actually knitted.</p> <p>21 Q. And what do you base that testimony on?</p> <p>22 A. Just documentation that I've reviewed.</p> <p>23 Q. Are you an expert in the manufacturing process</p> <p>24 of pelvic mesh?</p>
<p style="text-align: right;">Page 27</p> <p>1 A. No.</p> <p>2 Q. Do you know any of the nonsurgical options?</p> <p>3 A. No.</p> <p>4 Q. And, Doctor, all of your opinions contained in</p> <p>5 your report, which was marked as Exhibit 3, refer to</p> <p>6 these individual products; correct?</p> <p>7 A. Yes.</p> <p>8 Q. Doctor, do you know how many newtons of force</p> <p>9 are placed on the mesh once it's in vivo?</p> <p>10 A. No.</p> <p>11 Q. Do you have any idea about how these individual</p> <p>12 products are implanted in the body?</p> <p>13 A. I have some idea.</p> <p>14 Q. Have you ever -- certainly you've never</p> <p>15 implanted any of these devices in the body?</p> <p>16 A. I have not.</p> <p>17 Q. Have you ever watched any videos regarding how</p> <p>18 these devices were implanted in the body?</p> <p>19 A. Not videos, but I have seen pictures showing</p> <p>20 how it's done, basically.</p> <p>21 Q. And do you know the differences in how these</p> <p>22 individual products are implanted in the body?</p> <p>23 A. No.</p> <p>24 Q. What do you know about the manufacturing</p>	<p style="text-align: right;">Page 29</p> <p>1 A. Well, I'm knowledgeable in the production of</p> <p>2 polypropylene fibers. When I was at Hercules, as I</p> <p>3 mentioned earlier, I was there for five years right</p> <p>4 after graduate school, for about three years of that</p> <p>5 time I was technical liaison between Hercules' central</p> <p>6 R & D center in Wilmington, Delaware, and Hercules'</p> <p>7 fibers technical center in Oxford, Georgia, where they</p> <p>8 produce polypropylene fibers on a massive scale.</p> <p>9 Q. Well, but do you hold yourself out as an expert</p> <p>10 in the manufacturing process of pelvic mesh?</p> <p>11 A. I'm certainly knowledgeable about production of</p> <p>12 polypropylene fibers. Once it gets into the actual</p> <p>13 knitting process and the exact geometry of these various</p> <p>14 mesh products, I'm not an expert in those areas.</p> <p>15 Q. Doctor, you know the difference between</p> <p>16 polypropylene and Prolene; correct?</p> <p>17 A. Yes.</p> <p>18 Q. And as a materials scientist, you'll agree that</p> <p>19 polypropylene is chemically different than Prolene;</p> <p>20 correct?</p> <p>21 A. Well, Prolene is mostly polypropylene. It's</p> <p>22 isotactic polypropylene, to be exact.</p> <p>23 Q. I understand.</p> <p>24 A. But it does contain additives, but those</p>

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<p style="text-align: right;">Page 30</p> <p>1 additives are present at a very low level.</p> <p>2 Q. But to be exact, polypropylene is chemically</p> <p>3 different than Prolene; correct?</p> <p>4 A. Well, polypropylene as it's encountered in the</p> <p>5 marketplace essentially always has these additives in</p> <p>6 it. Processing aids and antioxidants are always put</p> <p>7 into polypropylene.</p> <p>8 Q. Right, but, Doctor, my question is more</p> <p>9 specific. Is it your testimony that polypropylene and</p> <p>10 Prolene are chemically different or chemically the same?</p> <p>11 A. Prolene is a particular formulation of</p> <p>12 polypropylene.</p> <p>13 Q. So they're chemically different; correct?</p> <p>14 A. There are additives added.</p> <p>15 Q. But they are chemically different?</p> <p>16 Polypropylene is chemically different than Prolene;</p> <p>17 correct?</p> <p>18 A. Well, Marlex versus Prolene, the base polymer</p> <p>19 in both is isotactic polypropylene. There may be</p> <p>20 different additives in there. There may be different</p> <p>21 molecular weights of polypropylene use. There may be</p> <p>22 different molecular weight distributions of the</p> <p>23 polypropylene that's used. So Prolene is a particular</p> <p>24 formulation of polypropylene.</p>	<p style="text-align: right;">Page 32</p> <p>1 A. My biggest focus on polypropylene was when I</p> <p>2 was at Hercules. We performed a lot of analytical work</p> <p>3 on polypropylene. But I actually synthesized</p> <p>4 polypropylene and polypropylene copolymers and</p> <p>5 characterized the products when I was a graduate student</p> <p>6 at the University of Akron in the very early 1980s.</p> <p>7 Q. Have you ever done any independent study or lab</p> <p>8 work regarding the biocompatibility of polypropylene?</p> <p>9 A. Could you repeat that question?</p> <p>10 Q. Sure. Have you ever done any independent study</p> <p>11 or lab work regarding the biocompatibility of</p> <p>12 polypropylene?</p> <p>13 A. What do you mean by "biocompatibility"?</p> <p>14 Q. Whether or not polypropylene is biocompatible</p> <p>15 with the human body.</p> <p>16 A. You mean cell culture studies, things like</p> <p>17 that?</p> <p>18 Q. Whether it's biocompatible with the human body.</p> <p>19 A. Well, I've examined explanted polypropylene and</p> <p>20 seen degradation in the material.</p> <p>21 Q. Doctor, I may have asked you this. If I did, I</p> <p>22 apologize. You've never designed a polypropylene</p> <p>23 implant; correct?</p> <p>24 A. I have not.</p>
<p style="text-align: right;">Page 31</p> <p>1 Q. I understand that, Doctor, but Prolene has a</p> <p>2 different chemical composition compared to pure</p> <p>3 polypropylene; correct?</p> <p>4 A. Compared to pure polypropylene, that's correct.</p> <p>5 Q. Thank you. And Prolene and polypropylene are</p> <p>6 not identical from a chemical composition standpoint,</p> <p>7 are they?</p> <p>8 A. Polypropylene is the major component in</p> <p>9 Prolene.</p> <p>10 Q. Right, but they are not chemically identical,</p> <p>11 are they, sir?</p> <p>12 A. The additives make them different. Prolene has</p> <p>13 the additives. Pure polypropylene would not.</p> <p>14 Q. And you'd never teach your polymer students at</p> <p>15 UT that Prolene and polypropylene have the same chemical</p> <p>16 composition, would you?</p> <p>17 A. No, I would teach them that Prolene is an</p> <p>18 isotactic polypropylene with a certain additive package</p> <p>19 in it.</p> <p>20 Q. Let's talk about polypropylene specifically, if</p> <p>21 you will. You've studied polypropylene before, I take</p> <p>22 it, as a scientist?</p> <p>23 A. Yes.</p> <p>24 Q. When did you begin doing that?</p>	<p style="text-align: right;">Page 33</p> <p>1 Q. And -- well, let's talk about Prolene for a</p> <p>2 minute. Has any of the work that you've done as a</p> <p>3 scientist involved Prolene other than the litigation</p> <p>4 that we're here about today?</p> <p>5 A. As I said earlier, I've been involved with</p> <p>6 polymers for a long time. We've got our polymer</p> <p>7 characterization lab at the university. Something could</p> <p>8 have passed through, but I don't recall it.</p> <p>9 Q. Thank you. And, Doctor, have you ever done any</p> <p>10 type of study to determine the biocompatibility of</p> <p>11 Prolene?</p> <p>12 A. No.</p> <p>13 Q. And have you ever done any testing to determine</p> <p>14 if Prolene degrades?</p> <p>15 A. Well, we've done studies to determine whether</p> <p>16 or not polypropylene formulations degrade.</p> <p>17 Q. But, Doctor, my question is specifically about</p> <p>18 Prolene. Have you ever performed any testing to</p> <p>19 determine if Prolene degrades?</p> <p>20 A. I've reviewed the literature, including the</p> <p>21 literature in-house at Ethicon, where they observed what</p> <p>22 they attributed as oxidative degradation.</p> <p>23 Q. Doctor, have you ever performed any -- strike</p> <p>24 that.</p>

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<p style="text-align: right;">Page 34</p> <p>1 Have you personally performed any testing to 2 determine if Prolene degrades? 3 A. We have performed testing to determine whether 4 or not polypropylene -- 5 Q. And I'm not -- I don't mean to cut you off, but 6 I am under a time limit. I'm talking about Prolene. 7 Have you personally done any testing to 8 determine if Prolene degrades? 9 A. We have tested polypropylene pelvic mesh. That 10 was a Boston Scientific product. But these materials 11 are 99.8 percent polypropylene. 12 Q. And move to strike as nonresponsive. 13 Doctor, I'm asking you a specific question. I 14 need a yes or no. Have you personally performed any 15 testing to determine if Prolene degrades? 16 A. We have tested polypropylene, but we have not 17 tested Prolene. 18 Q. Thank you. And, Doctor, you've not tested the 19 mechanical properties of Prolene, have you? 20 A. We have not. 21 Q. Doctor, have you done any tests on Prolene that 22 can be repeated and confirmed? I'm talking about 23 Prolene, not polypropylene. 24 A. Yeah. We have not in my laboratory tested</p>	<p style="text-align: right;">Page 36</p> <p>1 Q. A reduction in the physical properties. 2 A. Which ones? 3 Q. Any of them. 4 A. Have I actually seen that material with my own 5 eyes? 6 Q. Yes, sir. 7 A. No. 8 Q. Thank you. And, in fact, Doctor, you've never 9 tested the durability of Prolene, have you? 10 A. No. 11 Q. You've never tested the tensile strength of 12 Prolene, have you? 13 A. No. 14 Q. You've never tested the toughness of Prolene, 15 have you? 16 A. No. 17 Q. You've never tested any type of physical 18 property of Prolene, have you? 19 A. No. 20 Q. You've never done any type of benchtop testing 21 of Prolene, have you? 22 A. No. 23 Q. And you've never done any root cause analysis 24 to determine if Prolene is defective, have you?</p>
<p style="text-align: right;">Page 35</p> <p>1 Prolene. 2 Q. Doctor, have you ever done -- and when you say 3 you have not in your laboratory tested Prolene, would 4 that include a pristine piece of Prolene and also an 5 explanted piece of Prolene? 6 A. Yeah, again, as I said earlier, we may have 7 characterized some material that was sent to us by 8 someone at some point, probably in terms of a molecular 9 weight analysis or something like that, but I don't 10 recall testing Prolene. 11 Q. Doctor, have you ever personally seen a Prolene 12 explant that has degraded? 13 A. I've seen pictures, but I haven't actually with 14 my own two eyes seen the degraded Prolene explant. 15 Q. And, Doctor, with your own two eyes, have you 16 ever seen oxidated Prolene? 17 A. With my own two eyes, I'd have to say no. 18 Q. Doctor, with your own two eyes, have you ever 19 personally seen Prolene with embrittlement? 20 A. No. 21 Q. Have you ever with your own two eyes personally 22 seen Prolene that has a loss of mechanical properties? 23 A. What do you mean by "loss of mechanical 24 properties"?</p>	<p style="text-align: right;">Page 37</p> <p>1 A. Yes, I think I have. 2 Q. What? 3 A. Basically, I reviewed extensive literature, 4 both Ethicon internal literature where they observed 5 degradation of explanted Prolene, and I also reviewed 6 extensive literature. I could go through paper by 7 paper, if you like, and they observed degradation of 8 Prolene implants. 9 Q. And we're going to get to that, but outside of 10 literature, Doctor, have you ever done any -- outside of 11 your literature review, have you ever done any type of 12 root cause analysis to determine if Prolene is 13 defective? 14 A. We have explored the mechanism by which 15 polypropylene mesh degrades inside the body. 16 Q. Okay. And I'm sorry if my question wasn't 17 clear. I was asking about Prolene. 18 So outside of literature, Doctor, have you ever 19 done any type of root cause analysis to determine if 20 Prolene is defective? 21 A. What do you mean by "root cause analysis"? 22 Q. Any type of analytical study to determine if 23 Prolene is defective. 24 A. You mean actually perform experiments on</p>

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<p style="text-align: right;">Page 38</p> <p>1 Prolene? No.</p> <p>2 Q. Doctor, have you ever performed any type of</p> <p>3 accelerated aging tests for Prolene?</p> <p>4 A. No.</p> <p>5 Q. Doctor, you've cleaned mesh before, have you</p> <p>6 not?</p> <p>7 A. Yes.</p> <p>8 Q. Have you personally been involved in that</p> <p>9 process?</p> <p>10 A. Yes, I have.</p> <p>11 Q. And was that with the 11 explants in Boston</p> <p>12 Scientific?</p> <p>13 A. Yes.</p> <p>14 Q. Have you ever personally cleaned Prolene mesh?</p> <p>15 A. No.</p> <p>16 Q. Have you ever been involved in any type of</p> <p>17 cleaning protocols for Prolene mesh?</p> <p>18 A. With developing the cleaning protocol?</p> <p>19 Q. For Prolene mesh. Not polypropylene. Prolene</p> <p>20 mesh.</p> <p>21 A. No, we haven't cleaned Prolene mesh.</p> <p>22 Q. And -- but you haven't been involved in any</p> <p>23 cleaning protocols for Prolene mesh; correct?</p> <p>24 A. There's an ASTM protocol, and that's what we</p>	<p style="text-align: right;">Page 40</p> <p>1 28 women?</p> <p>2 A. No.</p> <p>3 Q. Have you ever even seen the explants from these</p> <p>4 28 women?</p> <p>5 A. No.</p> <p>6 Q. Do you know if any exist?</p> <p>7 A. I don't.</p> <p>8 Q. Do you know why their mesh was removed?</p> <p>9 A. Because they had a problem. It's not ethical</p> <p>10 to take mesh out if a person's not having a problem with</p> <p>11 it.</p> <p>12 Q. What do you base that on?</p> <p>13 A. It's a horribly invasive surgery.</p> <p>14 Q. What problem did Bonnie Blake have, Doctor,</p> <p>15 that required her mesh to be removed?</p> <p>16 A. I don't know.</p> <p>17 Q. And, Doctor, what problem did Robin Bridges</p> <p>18 have that required her mesh to be removed?</p> <p>19 A. The specific complaints of the individuals, I</p> <p>20 don't know.</p> <p>21 Q. And, Doctor, do you know the specific reasons</p> <p>22 why any of the 28 plaintiffs' mesh were removed?</p> <p>23 A. As I said before, because they were having a</p> <p>24 problem with it.</p>
<p style="text-align: right;">Page 39</p> <p>1 use when we clean polypropylene.</p> <p>2 Q. Right, but I'm asking about your personal</p> <p>3 experience, Doctor. You've never been involved in any</p> <p>4 cleaning protocols for Prolene mesh; correct?</p> <p>5 A. No. Correct.</p> <p>6 Q. Doctor, look back at Exhibit 1 for me, please.</p> <p>7 That's a notice of deposition?</p> <p>8 A. Yes.</p> <p>9 Q. I'll represent to you that you're designated in</p> <p>10 28 different lawsuits. Does that look about right?</p> <p>11 A. That looks about right.</p> <p>12 Q. Do you know what -- and each lawsuit represents</p> <p>13 the name of a plaintiff that received a Prolene implant;</p> <p>14 correct?</p> <p>15 A. Correct.</p> <p>16 Q. Do you know what product these 28 women</p> <p>17 received?</p> <p>18 A. All I know is it was Prolene, a Prolene-based</p> <p>19 mesh.</p> <p>20 Q. You never reviewed medical records?</p> <p>21 A. No.</p> <p>22 Q. Never talked to any of the doctors?</p> <p>23 A. No.</p> <p>24 Q. Never inspected any of the explants from these</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. But my question is: Do you know the specific</p> <p>2 reason why any of these 28 plaintiffs' mesh was removed?</p> <p>3 A. No, I don't.</p> <p>4 Q. You don't know when these 28 plaintiffs' meshes</p> <p>5 were implanted, do you?</p> <p>6 A. I do not have those records, no.</p> <p>7 Q. And you don't know when they were explanted?</p> <p>8 A. No.</p> <p>9 Q. Do you know how many pieces of an explant was</p> <p>10 removed?</p> <p>11 A. No.</p> <p>12 Q. And do you know if these 28 plaintiffs'</p> <p>13 explants were stored in formalin?</p> <p>14 A. No.</p> <p>15 Q. You would agree that if explants exist for</p> <p>16 these 28 plaintiffs, that would be an important piece of</p> <p>17 evidence in this litigation; correct?</p> <p>18 A. That would be, yes.</p> <p>19 Q. And would you like to review those explants?</p> <p>20 A. Sure.</p> <p>21 Q. And have you asked the plaintiffs' lawyers for</p> <p>22 the permission to review those explants?</p> <p>23 A. I have not.</p> <p>24 Q. Why not?</p>

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<p style="text-align: right;">Page 42</p> <p>1 A. Well, I might very well at some point in time. 2 The first step was to get familiar with the case and 3 file my report. 4 Q. Doctor, have you ever seen any type of 5 histology slides from any of these 28 plaintiffs? 6 A. Not to my knowledge. 7 Q. Would you review histology slides if they were 8 available? 9 A. I'd certainly look at them. 10 Q. Have you asked for them? 11 A. I have not. 12 Q. Doctor, have you ever performed -- strike that. 13 Fair to say that you've never performed any 14 type of analytical testing on the explants of these 28 15 plaintiffs; correct? 16 A. Correct. 17 Q. You've never done any type of SEM, FTIR, DSC, 18 EDS, GPC on these plaintiffs' explants; correct? 19 A. Correct. 20 Q. Doctor, have you -- strike that. 21 I think we talked about this earlier, but it's 22 undisputed that degradation affects the physical 23 properties of mesh; correct? 24 A. Yes.</p>	<p style="text-align: right;">Page 44</p> <p>1 A. My experience with polypropylene, my 2 characterization of polypropylene-based meshes. 3 Q. Do you base -- 4 A. The literature that Ethicon has in-house going 5 back to the early '80s where they again and again see 6 evidence of oxidative degradation of polypropylene 7 implants. 8 Q. Doctor, you've never personally run any type of 9 oxidation tests on Prolene; correct? 10 A. To my knowledge, not on Prolene. 11 Q. And you've never done a molecular weight test? 12 A. We've done a lot of molecular weight tests. 13 Q. On Prolene? 14 A. As I said earlier, we may have in the polymer 15 characterization lab at some time, but I don't recall 16 explicitly doing molecular weight determinations on 17 Prolene. 18 Q. Okay. And you would have done that by GPC; 19 correct? 20 A. Yes. It's not the only way to determine 21 molecular weight, but it's a very common way to do it. 22 Q. And, Doctor, those analytical testing 23 techniques were available to you at your lab at UT; 24 correct?</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. And you've never performed any physical or 2 mechanical testing on the explants of these 28 3 plaintiffs; correct? 4 A. Correct. 5 Q. That would include tensile strength, 6 elongation, toughness, or Young's modulus; correct? 7 A. Correct. 8 Q. Also, we would include creep, stress, 9 relaxation, and fatigue; correct? 10 A. Correct. 11 Q. You've not done any of that? 12 A. Correct. 13 Q. Doctor, the tests, the analytical tests that we 14 just talked about, the SEMs, the FDIRs, those show 15 oxidation; correct? 16 A. Yes. 17 Q. And have you done any type of testing 18 whatsoever on these 28 plaintiffs to show oxidation? 19 A. I have not. 20 Q. And, Doctor, can you make any type of 21 prediction about whether or not the mesh from these 28 22 plaintiffs will oxidize? 23 A. Yes, I can. 24 Q. And what do you base that on?</p>	<p style="text-align: right;">Page 45</p> <p>1 A. We have those techniques available, yes. 2 Q. And, Doctor, when I asked you could you make 3 any prediction about whether or not the mesh from these 4 28 plaintiffs will oxidize, do you -- are you supporting 5 that opinion on any literature specifically about 6 Prolene? 7 A. Yes. 8 Q. What literature? 9 A. Okay. Let's look in my report. 10 Q. And I'm not talking about polypropylene. I'm 11 talking about Prolene. Okay? 12 A. Okay. 13 MR. MONSOUR: Just so you know, I've seen you 14 look at your watch about 20 times, we're not going 15 to hold your feet to the fire on three hours. I 16 mean, if you need some more time, let us know. 17 Within reason, but just let us know. 18 MR. HUTCHINSON: I appreciate it. 19 MR. MONSOUR: Don't worry. 20 A. The Reference 20 in my report, this is 21 Jongebloed, I guess that's how you say it, and Worst, 22 they reported an SEM study on a Prolene suture that had 23 been implanted in the human eye for one year, and they 24 reported that both Prolene loops showed severe</p>

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<p style="text-align: right;">Page 46</p> <p>1 degradation of the surface layer. 2 Then Mary, et al., in 1998, that's Reference 21 3 in my report, they looked at polypropylene, Prolene 4 sutures used in vascular surgery, and the explanted 5 suture showed visible evidence of surface stress 6 cracking. 7 Costello, et al., those are two papers from 8 2007. 9 Q. And did those -- but my question, sir, is about 10 Prolene. Did those Costello papers reference Prolene? 11 A. Yes. 12 Q. Okay. All right. Other than Jongebloed -- and 13 you spell that J-o-n-g-e-l-b-o-e-d [sic] -- 14 A. I'm not sure we're pronouncing it right. Who 15 knows? 16 Q. -- Mary and Costello -- 17 A. Yeah, there's two Costello papers. 18 Q. Correct. Any other literature that you're 19 supporting your opinions on? 20 A. Actually, Clave reports analysis of 100 21 explants, these were pelvic meshes from various 22 suppliers, but they're really not explicit about where 23 they came from, but it may well be that there are some 24 Ethicon materials in there.</p>	<p style="text-align: right;">Page 48</p> <p>1 or one could look at molecular weight changes in the 2 material. If chains are being broken, degradation is 3 happening. 4 Those changes manifest themselves in changes in 5 mechanical properties, but they're not the direct 6 observation of the degradation process. You're 7 measuring the consequences of degradation with those 8 studies. 9 Q. Doctor, but, nevertheless, evaluating 10 mechanical properties and physical properties are an 11 important part in your analysis of whether or not a 12 material degrades; correct? 13 A. No. As I just said, degradation can be 14 established with spectroscopy, with microscopy, with gel 15 permeation chromatography, with light scattering, and 16 other molecular methods. 17 Q. Can degradation be established by reduction in 18 physical properties? 19 A. If one measures a material and sees a reduction 20 in mechanical properties, again, just speaking 21 generically about mechanical properties at this point, 22 if one sees a change, then one might suspect degradation 23 is taking place, yes. 24 Q. All right. And just so the record's clear,</p>
<p style="text-align: right;">Page 47</p> <p>1 Q. But you don't know for sure, do you, sir? 2 A. Not in the case of Clave. 3 Q. Okay. Thank you. 4 A. I haven't seen firm evidence. But then I've 5 also got the internal Ethicon documents. 6 Q. We're going to get to those in a minute, but 7 I'm talking about the peer-reviewed literature. Okay? 8 A. Okay. 9 Q. So we'll get to those in a minute, but let's 10 stick with the peer-reviewed literature. 11 A. Okay. 12 Q. Jongebloed, Mary, and Costello are the only 13 literature regarding Prolene that you base your opinions 14 on; is that correct? 15 A. Yes. 16 Q. Okay. And, Doctor, I forgot to ask you about 17 this earlier, but when we were talking about physical 18 and mechanical property testing, you'll agree that 19 mechanical properties and the evaluation of mechanical 20 properties is relevant when determining whether or not 21 mesh degrades? 22 A. I don't think it's necessarily relevant. One 23 can determine if a material is degrading by 24 spectroscopic means, chemical changes in the material,</p>	<p style="text-align: right;">Page 49</p> <p>1 degradation can be established by reduction in physical 2 properties; correct? 3 A. No, molecular level degradation needs 4 spectroscopy or molecular weight measurements. 5 Mechanical properties -- changes in mechanical 6 properties are merely an outcome of the chemical 7 changes. They're not direct. 8 Q. Doctor, would you ever tell your students at UT 9 to disregard the results of physical properties when 10 making a determination of whether or not a polymer has 11 degraded? 12 A. Well, if they had that material at hand, 13 certainly they would factor it into the analysis, but 14 it's not the direct analysis of whether or not a 15 material has degraded. 16 Q. I understand that, sir, but you will agree that 17 it is one piece of the puzzle on whether or not a 18 polymer has degraded; correct? 19 A. It's a piece of the puzzle, but it's a 20 secondary piece of the puzzle. It's not a primary one. 21 Q. Doctor, do you have any evidence that any of 22 these 28 plaintiffs experienced any type of chronic pain 23 related to Prolene? 24 A. No direct evidence, but they had their mesh</p>

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<p style="text-align: right;">Page 50</p> <p>1 taken out, and I assume they had problems with it, or 2 they wouldn't be suing Ethicon. 3 Q. That's an assumption on your part; correct? 4 A. It is. It is. 5 Q. And, Doctor, can you identify by name a single 6 person who has had a failure of their mesh for the 7 reasons that you outline in your report? 8 A. I would say that oxidative degradation is at 9 the heart of the problems that all of these people had 10 with the mesh and it's the reason that there's multiple 11 mesh companies with thousands of lawsuits around. 12 People are having problems with polypropylene mesh. 13 It's fundamentally the wrong material to make a pelvic 14 mesh out of. 15 Q. Doctor, can you identify by name a single 16 person who has had a failure of their mesh for the 17 reasons outlined in your report? 18 A. Again, all these people -- 19 Q. I'm just asking for a name. 20 A. All of these people, Bonnie Blake, Robin 21 Bridges, Carey Beth Cole, these people had problems with 22 their mesh. 23 Q. How did Bonnie Blake's mesh fail? 24 A. Oxidative degradation is at the core of what's</p>	<p style="text-align: right;">Page 52</p> <p>1 of these removals, so every individual listed here. 2 Q. Okay. And, Doctor, how do you know that Bonnie 3 Blake's mesh was removed because of degradation without 4 reviewing the medical records? 5 A. It's made out of polypropylene. Polypropylene 6 is attacked inside the human body with strong oxidizing 7 agents. 8 Q. Does Bonnie Blake have any mesh that's made out 9 of Prolene? 10 A. I have to assume that her mesh was made out of 11 Prolene because she's suing Ethicon. 12 Q. Do you know if Bonnie Blake has mesh that's 13 made out of Prolene? 14 A. I think it's a logical conclusion to reach. 15 Q. My question is: Do you know, sir, whether or 16 not Bonnie Blake has mesh that's made out of Prolene? 17 A. I have not reviewed her medical records. Okay? 18 Q. But my question is: Do you know if Bonnie 19 Blake has mesh that's made out of Prolene? Yes or no? 20 A. Yes. 21 Q. And what do you base that on? 22 A. The fact that she's suing Ethicon. 23 Q. Doctor, you're not a clinician? 24 A. I'm not.</p>
<p style="text-align: right;">Page 51</p> <p>1 happening to these materials inside the human body. 2 Q. And, Doctor, my question is: If you've not 3 reviewed Bonnie Blake's explant, how can you tell the 4 jury that Bonnie Blake's explant failed because of 5 oxidative degradation? 6 A. We have examined explants, to the extent that 7 we could lay our hands on them, and there's indication 8 of oxidative degradation in all the ones that we've 9 seen. 10 Q. I understand that, but you've never examined 11 Bonnie Blake's explant, have you? 12 A. I have not. 13 Q. And, Doctor, can you identify by name a person 14 who has had mesh removed because of specifically 15 degradation? 16 A. Well, again, it's what I'm saying. There's 17 this list of women here, and they had problems with 18 their mesh. And polypropylene is fundamentally 19 susceptible to oxidative degradation. It's inherent to 20 its chemical structure. 21 Q. Doctor, can you identify the name of a person 22 who has had their mesh specifically removed because of 23 degradation? 24 A. I believe oxidative degradation is behind all</p>	<p style="text-align: right;">Page 53</p> <p>1 Q. And you haven't -- have you ever reviewed a 2 medical record that says the surgeon is removing Prolene 3 mesh as a result of degradation? 4 A. I don't review medical records normally. I'm a 5 polymer scientist. I'm a polymer chemist. The 6 chemistry of polymers, the characterization of polymers, 7 is my thing. I'm not a medical doctor. 8 Q. I understand that, Doctor, but my question is: 9 Have you ever reviewed a medical record that says a 10 surgeon is removing Prolene mesh as a result of 11 degradation? 12 A. I have not. 13 Q. Doctor, have you done anything whatsoever to 14 explain how the alleged effects of degradation have 15 caused clinical harm to any of these 28 plaintiffs? 16 A. Well, my report describes what happens to the 17 properties of polypropylene when they undergo 18 degradation, and it's the mechanical mismatch between 19 the degraded implants and the soft tissue that surrounds 20 it that's the root cause of these problems. 21 Q. Do you know the symptoms that any of these 28 22 plaintiffs were complaining about? 23 A. Individual symptoms will vary, but pain is a 24 very common one.</p>

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<p style="text-align: right;">Page 54</p> <p>1 Q. Do you -- but do you know the specific symptoms 2 of these 28 plaintiffs in these cases that you're 3 designated as an expert in? 4 A. No, I don't. 5 Q. And, Doctor, are you qualified to teach 6 students at UT how degradation can cause clinical harm? 7 A. Yes, I am. I've taught a lot of biomedical 8 students in the past. 9 Q. And, Doctor, have you ever taught any students 10 at UT that degradation causes clinical harm? 11 A. Certainly I have done that, yes. 12 Q. And, Doctor, have you ever taught any of your 13 students at UT how Prolene causes clinical harm? 14 A. Explicitly with Prolene, no, but with a variety 15 of biomaterials, whether it's bone cement or what have 16 you. Degradation is a bad thing. 17 Q. And, Doctor, have you ever taught your students 18 at UT anything about Prolene? 19 A. Yes. I teach them about polypropylene, and 20 Prolene is made of polypropylene. 21 Q. Doctor, have you ever taught your students 22 about Prolene specifically? 23 A. Specifically by name, Prolene, no, but 24 isotactic polypropylene with the usual package of</p>	<p style="text-align: right;">Page 56</p> <p>1 Q. And, Doctor, are you aware that a West Virginia 2 federal judge ruled that your testing of the Boston 3 Scientific products was unreliable and excluded it? 4 A. That's correct, but those data were eventually 5 published in the top biomaterials journal in the world 6 after undergoing, not only rigorous peer review, but 7 also the paper was reviewed for merit by the editorial 8 advisory board because the work was done under 9 litigation, for litigation purposes. 10 Q. Doctor, have you ever done any type of testing 11 of mesh explants that's been admitted in a court? 12 A. Not yet. 13 Q. In the Boston Scientific, Doctor -- I'm sorry. 14 Strike that. 15 In the Boston Scientific litigation, you 16 testified that you're not an expert in the design of 17 surgical mesh. Do you stand by that? 18 A. I'm not an expert in the design of surgical 19 mesh. I'm an expert in the polymers that the surgical 20 meshes are made of, whether they're polypropylene, 21 polyethylene terephthalate, polyvinylidene fluoride. 22 I'm knowledgeable broadly about polymer chemistry and 23 characterization of polymers. 24 MR. MONSOUR: At the end of this, you're going</p>
<p style="text-align: right;">Page 55</p> <p>1 additives, such as processing aids and antioxidants, 2 yes. 3 Q. Doctor, I know that you've worked for -- 4 against, rather -- Boston Scientific. Have you ever 5 done any type of analytical testing of pelvic mesh 6 explants other than in Boston Scientific? 7 A. No. 8 Q. And, Doctor, are you -- did you perform any 9 type of physical property testing of the pelvic explants 10 in the Boston Scientific litigation? 11 A. We measured the materials by spectroscopy, we 12 did GPC, we looked at the materials with 13 thermogravimetric analysis, SEM with EDS, but we did not 14 measure mechanical properties of those materials. 15 Q. Why not? 16 A. We were interested in determining what caused 17 the degradation of those materials once we noted the 18 degradation, and we used spectroscopy and GPC to do it. 19 As I mentioned earlier, those are the primary tools that 20 one would use to get direct evidence of degradation and 21 to identify what's causing the degradation. 22 Q. Doctor, you'll agree that the adherence to 23 protocols and controls is the hallmark of good science? 24 A. Yes.</p>	<p style="text-align: right;">Page 57</p> <p>1 to have to spell, probably, a few of those. 2 THE WITNESS: We'll do that. 3 MR. HUTCHINSON: Yeah. 4 THE WITNESS: We'll do that. 5 BY MR. HUTCHINSON: 6 Q. But -- I'm sorry. You're not an expert in the 7 design of surgical mesh? 8 A. Actually designing the mesh, the geometry, the 9 shape, no, I'm not. 10 Q. And, Doctor, you testified in Boston Scientific 11 that polypropylene meshes should not be available to 12 doctors to treat SUI or POP. Do you recall that? 13 A. Yes. 14 Q. And do you stand by that? 15 A. Yes, I do. 16 Q. Doctor, you testified that polypropylene 17 vaginal mesh is a very bad idea. Do you stand by that? 18 A. I do. 19 Q. And you've never shared those views with any 20 physicians at UT; is that right? 21 A. Yes, I have. 22 Q. When did you do that? 23 A. I did that late summer/early fall of last year. 24 Q. And you did that after you were cross-examined</p>

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<p style="text-align: right;">Page 58</p> <p>1 about that; correct?</p> <p>2 A. Yeah, I did.</p> <p>3 Q. Doctor, have you ever told the doctors at UT</p> <p>4 that Prolene mesh should not be used to treat SUI or</p> <p>5 POP?</p> <p>6 A. I cautioned them about polypropylene mesh</p> <p>7 broadly.</p> <p>8 Q. Okay. But my question is specifically about</p> <p>9 Prolene. Have you ever told the doctors at UT that</p> <p>10 Prolene mesh should not be used to treat SUI or POP?</p> <p>11 A. When I told them that polypropylene mesh should</p> <p>12 not be used, that it's a bad idea, that it's susceptible</p> <p>13 to degradation inside the human body, they should know</p> <p>14 that Prolene is polypropylene-based pelvic mesh, just</p> <p>15 like Marlex is.</p> <p>16 Q. But, Doctor, have you ever told doctors at UT</p> <p>17 that using Prolene mesh should not be done in treating</p> <p>18 SUI or POP?</p> <p>19 A. Not yet.</p> <p>20 Q. Doctor, you testified in the Boston Scientific</p> <p>21 litigation that you couldn't cite any literature that</p> <p>22 states there's a clinical effect of degradation on a</p> <p>23 patient. Do you remember that?</p> <p>24 A. Yes, I do.</p>	<p style="text-align: right;">Page 60</p> <p>1 with this soft vaginal tissue, but as the oxidative</p> <p>2 process takes place, the mesh stiffens, and then it can</p> <p>3 no longer move with that material.</p> <p>4 So you've got soft flesh moving and the mesh</p> <p>5 isn't moving, so there's an abrasion, and this is a sort</p> <p>6 of thing that can lead to the abrasions that are seen</p> <p>7 with this mesh.</p> <p>8 Q. Doctor, stick with me. Are you aware of any</p> <p>9 literature that states there's a clinical effect of</p> <p>10 Prolene degradation on a patient? That's my question.</p> <p>11 A. I may have -- I may very well have seen that in</p> <p>12 all of my literature review, but I can't call it out as</p> <p>13 I sit here right at this moment.</p> <p>14 Q. And you didn't cite any reference in your</p> <p>15 report that says there's a clinical effect of Prolene</p> <p>16 degradation on a patient; correct?</p> <p>17 A. Actually, on thinking about it, I think this</p> <p>18 Klinge article, Reference 42, calls this out.</p> <p>19 Q. And what does it say about the clinical effect</p> <p>20 of Prolene degradation on a patient?</p> <p>21 MR. MONSOUR: I'm going to object to form. Can</p> <p>22 I ask you one question just for clarity's sake? Are</p> <p>23 you talking about polypropylene articles, or are you</p> <p>24 talking --</p>
<p style="text-align: right;">Page 59</p> <p>1 Q. And, Doctor, to this day, are you still unaware</p> <p>2 of any literature that states there's a clinical effect</p> <p>3 of degradation on the patient?</p> <p>4 A. No. I've gone and reviewed literature.</p> <p>5 Q. And, Doctor, are you aware of any literature</p> <p>6 that states there's a clinical effect of degradation on</p> <p>7 the patient?</p> <p>8 A. Yes.</p> <p>9 Q. And what literature is that?</p> <p>10 A. The book by Williams is the key reference.</p> <p>11 Q. What's the name of the book?</p> <p>12 A. Let me find it. It's in my reference list</p> <p>13 here.</p> <p>14 Yeah, it's Reference 44, Essential Biomaterials</p> <p>15 Science.</p> <p>16 Q. And that's the key reference that you rely on?</p> <p>17 A. Yes.</p> <p>18 Q. Doctor, does the Williams book say anything at</p> <p>19 all about the clinical effect of degradation of Prolene?</p> <p>20 A. I don't recall it calling out Prolene by name,</p> <p>21 but it basically lays out that implants have to be</p> <p>22 mechanically compatible with the tissue that they're</p> <p>23 implanted in, and initially a polypropylene mesh,</p> <p>24 including the Ethicon meshes, are supple and they move</p>	<p style="text-align: right;">Page 61</p> <p>1 MR. HUTCHINSON: Prolene.</p> <p>2 MR. MONSOUR: -- about, like, medical articles?</p> <p>3 MR. HUTCHINSON: I'm talking about any medical</p> <p>4 article referring to Prolene, which is different</p> <p>5 than polypropylene.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Doctor, that's the question.</p> <p>8 MR. MONSOUR: You can answer. You can answer.</p> <p>9 The only thing I'm trying to get at is just -- you</p> <p>10 can keep asking your question.</p> <p>11 A. You know, I'd have to go back and look at this</p> <p>12 Reference 42 to make absolutely sure, but I believe that</p> <p>13 one does call out Prolene by name. I believe he was</p> <p>14 actually a consultant with Ethicon at the time, and so</p> <p>15 he was looking at their materials.</p> <p>16 Q. Doctor, in Boston Scientific you testified</p> <p>17 you're not an expert in the biological response to</p> <p>18 foreign bodies. Do you stand by that?</p> <p>19 A. Well, I don't do research in that area day in</p> <p>20 and day out, so I'm not a card-carrying expert in that</p> <p>21 area, but I understand a bit about it, a bit about what</p> <p>22 the body does to foreign matter when it's placed inside</p> <p>23 it. So I'm not -- I'm not ignorant about it. I'm just</p> <p>24 not --</p>

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<p style="text-align: right;">Page 62</p> <p>1 Q. And, Doctor, you testified in the Boston 2 Scientific trial about degradation, didn't you? About 3 degradation? 4 A. Can you be more specific? 5 Q. Well, in the Boston Scientific trial, when you 6 gave opinions -- strike that. 7 In the Boston Scientific litigation, did you 8 give opinions about degradation without knowing what 9 antioxidants were put into the product? 10 A. I gave opinions about degradation of 11 polypropylene in general and about degradation of 12 polypropylene with antioxidants added, and I knew what 13 antioxidants were added, just as I know what 14 antioxidants were added to the Prolene. 15 Q. And, Doctor, is it your testimony under oath 16 that you knew what antioxidants were added to Boston 17 Scientific's products before you gave opinions about 18 degradation? 19 A. I did not know initially exactly what additives 20 were in there, but later on as I worked more on that 21 case I gained information on the antioxidants were 22 there. The expert on Boston Scientific's side actually 23 denied that antioxidants were in there at the beginning. 24 Q. Doctor, you'll agree with me that there's been</p>	<p style="text-align: right;">Page 64</p> <p>1 A. I don't know. That's all that comes to mind 2 now. 3 Q. Doctor, since your deposition -- by the way, 4 the last time you were deposed was in December of 2014; 5 correct? 6 A. In the Boston Scientific matter, yeah, I think 7 so. That sounds about right. But I've actually been 8 deposed in another matter since then. 9 Q. Was it a matter relating to vaginal mesh? 10 A. No. 11 Q. What was it about? 12 A. It was about surgical sealants. It was a 13 patent dispute. 14 Q. Have anything to do with polypropylene? 15 A. No. 16 Q. Doctor, since your last deposition in the mesh 17 litigation in 2014, have you undertaken any type of 18 investigation as to why there's been long-term effective 19 use of Prolene in the human body? 20 A. Certainly I've read a lot of literature about 21 the use of Prolene as a biomaterial. And, you know, a 22 little surface cracking caused by oxidation isn't a big 23 issue if you're using the material as a suture. The 24 material can become stiffer and still perform. The</p>
<p style="text-align: right;">Page 63</p> <p>1 a long-term effective use of Prolene in the human body? 2 A. Yes. I don't -- I don't condemn polypropylene 3 broadly as a biomaterial. It has applications, 4 certainly, in sutures. That's fine. It's been used for 5 a long time there. 6 Q. Do you condemn Prolene for use in the human 7 body? 8 A. As a vaginal mesh, as a pelvic mesh, yes. 9 Q. For a vaginal mesh only? 10 A. There are issues with it in possibly other 11 applications, but I -- because it is degrading. There 12 is oxidative degradation that's taking place in the 13 material. 14 Q. Right, but my question is for vaginal mesh 15 only. 16 A. Yes, I think -- I think Prolene is a very bad 17 idea for vaginal mesh. 18 Q. And vaginal mesh only; correct? 19 A. No, I wouldn't -- I wouldn't say that. It 20 could extend to other applications. 21 Q. Where else do you condemn the use of Prolene in 22 the human body? 23 A. There may be issues with hernia mesh. 24 Q. Where else?</p>	<p style="text-align: right;">Page 65</p> <p>1 suture's put in; the body heals quickly. Right? 2 But this mesh is designed to be a permanent 3 implant and it's designed to move with the body. One 4 has to consider the function that the material is going 5 to be used for inside the body. 6 Q. Doctor, you know that sutures, Prolene sutures, 7 are designed to be permanently implanted in the body, 8 don't you? 9 A. Yes, I do. 10 Q. And, Doctor, you know that hernia mesh is 11 designed to be permanently implanted in the body, don't 12 you? 13 A. I do. 14 Q. Doctor, since 2014, your last deposition, have 15 you found any scientific or medical literature that says 16 Prolene should not be used for mesh implants in the 17 human body? 18 A. Actually, I have. I've seen Ethicon's own 19 documentation, which indicates that Prolene is far from 20 an ideal material. 21 Q. I'm asking you, sir, about scientific 22 literature, medical literature. 23 A. Well, this is literature, internal literature, 24 but it's from Ethicon scientists.</p>

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<p style="text-align: right;">Page 66</p> <p>1 Q. Doctor, my question is about peer-reviewed 2 literature. Have you seen any peer-reviewed literature 3 that says Prolene should not be used as mesh implants in 4 the human body? 5 A. Well, I can go back to the Clave paper. They 6 looked broadly at polypropylene meshes from a variety of 7 suppliers. 8 Q. Did Clave conclude that Prolene mesh should not 9 be used in the human body? 10 A. They've had issues with use of 11 polypropylene-based meshes. 12 Q. But did they conclude that Prolene mesh should 13 not be used in the human body? 14 A. Not explicitly. 15 Q. Are you aware of any other article, Doctor? 16 A. Costello. 17 Q. That says -- that concludes -- my question is 18 specific. Are you aware of any peer-reviewed literature 19 that says Prolene mesh should not be used in the human 20 body? 21 A. I'm not aware of any literature that has that 22 exact statement in there. 23 Q. Doctor, have you ever told the doctors at UT 24 that Prolene mesh should not be used for hernia repair?</p>	<p style="text-align: right;">Page 68</p> <p>1 soft pelvic tissue in a woman. And being a mesh, tissue 2 grows into it, nerves grow into it, and when the 3 oxidative degradation occurs and the polypropylene 4 stiffens, the mesh can no longer move in concert with 5 that soft tissue that it's implanted in, so this creates 6 a sliding force or friction. 7 And in my report I liken it to taking fine 8 fishing line, which is basically what this mesh is, 9 polypropylene is widely used as fishing line, and 10 rubbing it across delicate skin. If you've been fishing 11 and you've done that, it can hurt. And that's what's 12 happening. That's the root cause of the pain. 13 Q. And, Doctor, in your fishing line example, if 14 the fishing line was oxidized, would it have cracks on 15 the outer layer? 16 A. If it's oxidized, it will have cracks on the 17 outer layer. 18 Q. And in your fishing line example, would those 19 cracks on the outer layer reduce physical properties of 20 the fishing line? 21 A. Cracks can certainly reduce physical 22 properties. 23 Q. It would reduce the toughness of the fishing 24 line?</p>
<p style="text-align: right;">Page 67</p> <p>1 A. I cautioned them about use of polypropylene 2 mesh broadly, that the material is degrading, whether 3 it's hernia or pelvic. 4 Q. But have you ever told doctors at UT that 5 Prolene mesh should not be used for hernia repair? 6 A. Explicitly Prolene by name, no, but when I say 7 "polypropylene mesh," logically that includes the whole 8 range of manufacturers, including Prolene. 9 Q. And, Doctor, have you concluded that -- have 10 you ever concluded that Prolene is toxic to the human 11 body? 12 A. I have not. 13 Q. Doctor, can you tell us the mechanism of action 14 by which oxidation causes pain in the human body? 15 A. Yes, I can. Oxidation in polypropylene takes 16 place in the amorphous regions of the polypropylene. 17 Polypropylene is really a composite. It's about half 18 crystals. That's what gives polypropylene its strength. 19 Q. Well, I'm going to get to the -- we're actually 20 going to get to that in just a minute. My question is 21 about how the mechanism of action of oxidation causes 22 pain in the human body. 23 A. Okay. Oxidation causes the mesh to stiffen. 24 The mesh is designed to be flexible and to move with the</p>	<p style="text-align: right;">Page 69</p> <p>1 A. It would reduce toughness. 2 Q. It would reduce the tensile strength of the 3 fishing line? 4 A. It would reduce tensile strength if those 5 cracks were large enough. 6 Q. Doctor, you know that Ethicon has a long 7 history of use of Prolene sutures, don't you? 8 A. Yes. 9 Q. Do you know how long the sutures have been on 10 the market? 11 A. Many years. Probably around 50 years. 12 Q. And do you know if the sutures, Ethicon 13 sutures, were approved by FDA as safe and effective? 14 A. I must assume that they were, yes. 15 Q. Doctor, do you have any criticisms whatsoever 16 regarding Ethicon's Prolene sutures? 17 A. No, I think the sutures are perfectly fine. 18 Q. Doctor, is it your testimony that patients -- 19 strike that. 20 Doctor, is it your opinion that every doctor 21 who uses a Prolene mesh product for pelvic floor repair 22 is committing malpractice? 23 A. No. 24 Q. Doctor, what about the surgeons, the implanting</p>

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<p style="text-align: right;">Page 70</p> <p>1 surgeons for these 28 plaintiffs, Ms. Bonnie Blake, all 2 the way down through Ms. Wroble, did these doctors 3 commit malpractice by using a Prolene implant in these 4 plaintiffs? 5 A. I don't believe they did. They used a product 6 that Ethicon represented to them was safe for use. 7 Q. Doctor, do you know what "the gold standard" 8 means? 9 A. I've certainly heard the term. 10 Q. Have you ever heard or read that TVT is known 11 as the gold standard? 12 A. I have read that. 13 Q. And, Doctor, do you disagree with the doctors 14 and scientists who have called TVT the gold standard? 15 MR. MONSOUR: Objection. Form. 16 A. Could you repeat the question? 17 Q. Do you disagree with the doctors and scientists 18 who have called TVT the gold standard? 19 MR. MONSOUR: Objection. Form. 20 A. They can certainly call it the gold standard. 21 That's fine. That's their opinion. 22 Q. Do you disagree with that? 23 A. I do. I'm an expert in the material that these 24 meshes are made of, and the mesh, in my opinion, is</p>	<p style="text-align: right;">Page 72</p> <p>1 but there's a certain percentage of people that do. 2 Q. Do you know that percentage? 3 A. Well, I don't, and I'm not here to guess. 4 Q. Okay. Doctor, what would the gold standard be, 5 in your opinion, for the material used to treat pelvic 6 floor repair? 7 A. From the literature I've reviewed, it looks 8 like polyvinylidene fluoride might be a better choice. 9 Q. PVDF; is that correct? 10 A. Yes. It looks like PET might also be a better 11 choice. 12 Q. And what does PET stand for? 13 A. Polyethylene terephthalate. 14 Q. And PVDF is polyvinylidene fluoride; correct? 15 A. Yes. 16 Q. And, Doctor, is it your testimony that -- which 17 one is -- well, let me back up. 18 Are you aware of any other materials that 19 should be used for pelvic floor repair other than PVDF 20 and PET? 21 A. I think those are the ones that people have 22 done some studies on and they show some promising 23 results. 24 Q. And is it your testimony that PVDF and PET are</p>
<p style="text-align: right;">Page 71</p> <p>1 unsuitable for use in pelvic applications. 2 Q. Doctor, is it your opinion that every person 3 who has had a Prolene vaginal mesh implant will 4 experience product failure? 5 A. Not everyone will experience product failure. 6 People are different. There can be -- you can put the 7 same mesh in two different people and they'll respond 8 differently. 9 But what I do believe is, if you leave that 10 mesh in there long enough, you will have oxidative 11 degradation of that mesh occurring, and it will stiffen. 12 Q. And that would be for hernia repair too? 13 A. Yes. 14 Q. Doctor, how can you tell which particular 15 person will have product failure that have received a 16 Prolene vaginal mesh? 17 A. I don't know. 18 Q. And, Doctor, is it your opinion that every 19 person who has had a Prolene hernia mesh implant will 20 experience product failure? 21 A. No. 22 Q. Why not? 23 A. Well, the record bears it out. A lot of people 24 have these implants and they never experience problems,</p>	<p style="text-align: right;">Page 73</p> <p>1 the safer alternatives than Prolene, Doctor? 2 A. They're less susceptible to degradation inside 3 the human body. 4 Q. Are they safer alternatives than Prolene, 5 Doctor? 6 A. More studies would have to be carried out. 7 Q. Can you testify to a reasonable degree of 8 scientific certainty whether or not PVDF and PET are 9 safer alternatives compared to Prolene? 10 A. I can only say that they're less susceptible to 11 degradation inside the human body. 12 Q. My question, sir, can you testify to a 13 reasonable degree of scientific certainty on whether or 14 not they are safer alternatives compared to Prolene? 15 Yes or no? 16 A. No, I'd need more data. 17 Q. Doctor, are you aware of any -- and, by the 18 way, which material are you advocating, PVDF or PET? 19 A. I'm not really an advocate for any of these 20 materials. 21 Q. Which materials do you believe would be safer 22 between PVDF and PET? 23 A. I'm not here to testify about that. I'm here 24 to testify that polypropylene, including Prolene, is a</p>

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<p style="text-align: right;">Page 74</p> <p>1 bad choice.</p> <p>2 Q. Do you have an opinion, sir, to a reasonable</p> <p>3 degree of scientific certainty on whether or not PVDF or</p> <p>4 PET is a safer alternative?</p> <p>5 A. I think they're worth investigating.</p> <p>6 Q. Can you make a difference between the two?</p> <p>7 A. No.</p> <p>8 Q. Doctor, are you aware of any medical device on</p> <p>9 the planet that's made out of PVDF for use in vaginal</p> <p>10 reconstructive surgery?</p> <p>11 A. The actual product name? I could go into some</p> <p>12 of these papers and find out. Would you like for me to?</p> <p>13 Q. Yeah, I'd like for you to --</p> <p>14 A. We can go to the Mary, for example.</p> <p>15 Q. My question, sir, are you aware of any mesh,</p> <p>16 vaginal mesh, on the market that is made out of PVDF?</p> <p>17 A. I am not aware of one.</p> <p>18 Q. And, Doctor, you've never tested the</p> <p>19 durability, the tensile strength, or the toughness of</p> <p>20 PVDF or PET, have you?</p> <p>21 A. We have done some testing of PET for sure.</p> <p>22 Q. What about PVDF?</p> <p>23 A. I don't believe we have.</p> <p>24 Q. And, Doctor, would you ever give PVDF a</p>	<p style="text-align: right;">Page 76</p> <p>1 comprised of proteins?</p> <p>2 A. Tissue's certainly got proteins in there.</p> <p>3 Q. And do you know the adhesion properties of PVDF</p> <p>4 compared to Prolene?</p> <p>5 A. I haven't measured those, no.</p> <p>6 Q. Fair to say, based on your chemical background,</p> <p>7 Doctor, that PVDF is a hybrid between polypropylene and</p> <p>8 Teflon?</p> <p>9 A. I would characterize it as more of a hybrid</p> <p>10 between polyethylene and Teflon.</p> <p>11 Q. Nevertheless, it's right in the middle; right?</p> <p>12 A. It's right in the middle, but that one methyl</p> <p>13 group makes a big difference on polypropylene.</p> <p>14 Q. And, Doctor, you've -- strike that.</p> <p>15 You've never designed a PVDF or PET implant of</p> <p>16 any kind; correct?</p> <p>17 A. I have not.</p> <p>18 Q. Doctor, could any mesh product be reasonably</p> <p>19 safe and effective for its intended use in the pelvic</p> <p>20 floor region?</p> <p>21 A. Repeat that, please.</p> <p>22 Q. Could any mesh product be reasonably safe and</p> <p>23 effective for use in the pelvic floor region?</p> <p>24 A. It's certainly possible, yes.</p>
<p style="text-align: right;">Page 75</p> <p>1 lifetime guarantee if it was implanted in a woman?</p> <p>2 A. I would need some more data before I would do</p> <p>3 that.</p> <p>4 Q. Same for PET?</p> <p>5 A. Yes.</p> <p>6 Q. PVDF is a different chemical composition of</p> <p>7 Prolene; correct?</p> <p>8 A. Yes.</p> <p>9 Q. So is PET?</p> <p>10 A. Yes.</p> <p>11 Q. And you've never done a study to determine</p> <p>12 whether or not PVDF or PET is a safer alternative;</p> <p>13 correct?</p> <p>14 A. I have not.</p> <p>15 Q. And are you aware of any literature that says</p> <p>16 PVDF or PET is a safer alternative than Prolene?</p> <p>17 A. No. As I said earlier, you asked me this</p> <p>18 before, I said that I've seen literature that says</p> <p>19 they're less susceptible to degradation inside the human</p> <p>20 body.</p> <p>21 Q. You've never done a study to determine whether</p> <p>22 or not tissue will adhere to PVDF, have you?</p> <p>23 A. I have not.</p> <p>24 Q. Okay. And you understand that tissue is</p>	<p style="text-align: right;">Page 77</p> <p>1 Q. And could you tell us what that composition</p> <p>2 consists of?</p> <p>3 A. I can tell you what it's not, and that's</p> <p>4 polypropylene.</p> <p>5 Q. Can you tell us what the composition should be,</p> <p>6 sir?</p> <p>7 A. I cannot.</p> <p>8 Q. Can you tell us the thickness?</p> <p>9 A. No.</p> <p>10 Q. Can you tell us the weave?</p> <p>11 A. No.</p> <p>12 Q. Can you tell us the pore size?</p> <p>13 A. No.</p> <p>14 Q. Can you tell us the tensile strength?</p> <p>15 A. No.</p> <p>16 Q. Can you tell us the density?</p> <p>17 A. No.</p> <p>18 Q. Are you aware of anybody who has done a</p> <p>19 design -- strike that.</p> <p>20 Doctor, as a materials scientist, are you aware</p> <p>21 of any material that's completely inert?</p> <p>22 A. No.</p> <p>23 Q. And, Doctor, are you aware of any product on</p> <p>24 the market for treatment of stress urinary incontinence</p>

20 (Pages 74 to 77)

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<p style="text-align: right;">Page 78</p> <p>1 or pelvic organ prolapse that is completely inert?</p> <p>2 A. No.</p> <p>3 Q. Doctor, are you aware of any medical device in</p> <p>4 the world that is completely inert?</p> <p>5 A. No.</p> <p>6 Q. Degradation. How do you define degradation?</p> <p>7 A. Change in the chemical structure.</p> <p>8 Q. And it also means a loss of molecular weight;</p> <p>9 correct?</p> <p>10 A. Well, again, we're back to where we were a</p> <p>11 couple of times previously. Degradation means a change</p> <p>12 in structure. It's detected with spectroscopy as</p> <p>13 introduction of different chemical groups. It can also</p> <p>14 be detected in polymers by degradation, decrease in the</p> <p>15 molecular weight.</p> <p>16 Mechanical properties are a consequence of</p> <p>17 the -- mechanical properties changes are a consequence</p> <p>18 of these chemical changes.</p> <p>19 Q. Doctor, have you ever testified that</p> <p>20 degradation means loss of molecular weight?</p> <p>21 A. That degradation means loss of molecular</p> <p>22 weight? Degradation of a polymer can certainly be loss</p> <p>23 of molecular weight, but you could have oxidative</p> <p>24 degradation of a material. In its early stages, you're</p>	<p style="text-align: right;">Page 80</p> <p>1 A. There will be reduction in molecular weight.</p> <p>2 And I want to be specific about molecular weight.</p> <p>3 Molecular weight is a term that gets tossed around</p> <p>4 loosely a lot with polymers, but there are different</p> <p>5 types of average molecular weights.</p> <p>6 Q. Right.</p> <p>7 A. Number average, weight average.</p> <p>8 Q. I'm going to get to those in just a minute.</p> <p>9 But if oxidation occurs, you must have cleavage of the</p> <p>10 polymer chain?</p> <p>11 A. Oxidative degradation of polypropylene does</p> <p>12 lead to chain cleavage, that's correct.</p> <p>13 Q. And oxidative degradation of Prolene leads to</p> <p>14 strong carbonyl bands present on FTIR that weren't there</p> <p>15 before; correct?</p> <p>16 A. Correct.</p> <p>17 Q. And strong -- I'm sorry.</p> <p>18 Oxidative degradation of Prolene leads to</p> <p>19 reduced physical properties; correct?</p> <p>20 A. It changes physical properties. It depends on</p> <p>21 the particular one whether it's reduced or not.</p> <p>22 Q. And when the polymer chain is cleaved, there's</p> <p>23 a reduction in physical properties; correct?</p> <p>24 A. Well, you have to specify which one.</p>
<p style="text-align: right;">Page 79</p> <p>1 actually increasing the molecular weight because you're</p> <p>2 incorporating oxygen into it.</p> <p>3 Q. Doctor, there must be a loss of molecular</p> <p>4 weight for degradation to occur; correct?</p> <p>5 A. Must be a loss of? Well, with polymers, if</p> <p>6 you're talking about oxidative degradation of</p> <p>7 polypropylene, you will see a reduction in molecular</p> <p>8 weight.</p> <p>9 Q. Thank you. And there must be -- there must be</p> <p>10 a reduction in molecular weight for degradation for a</p> <p>11 polymer; correct? You can't have one without the other?</p> <p>12 A. Degradation? Yes, you can. You can have</p> <p>13 chemical changes. Remember, I defined degradation as</p> <p>14 chemical changes in the polymer. You could have</p> <p>15 oxidation occurring at some level not to the point where</p> <p>16 it actually starts to cleave the chain and you will see</p> <p>17 increase in the molecular weight of the material.</p> <p>18 Q. But, Doctor, for oxidative degradation to</p> <p>19 occur, there must be loss of molecular weight; correct?</p> <p>20 A. Yes, when oxidative degradation of</p> <p>21 polypropylene occurs, there is degradation of molecular</p> <p>22 weight.</p> <p>23 Q. And when oxidative degradation of Prolene</p> <p>24 occurs, there must be loss of molecular weight; correct?</p>	<p style="text-align: right;">Page 81</p> <p>1 Q. All right. My question, sir, is the polymer</p> <p>2 chain of Prolene. When the polymer chain of Prolene is</p> <p>3 cleaved, there will be a reduction in physical</p> <p>4 properties?</p> <p>5 A. Again, it's which one? Are you talking about</p> <p>6 tensile strength? Are you talking about compliance?</p> <p>7 Are you talking about modules?</p> <p>8 Q. I'm talking about, actually, any physical</p> <p>9 property.</p> <p>10 A. Well, the tensile strength when molecular</p> <p>11 weight decreases will generally decrease. Tensile</p> <p>12 strength will decrease. But if you have this oxidative</p> <p>13 degradation occurring in the material, the modulus of</p> <p>14 the material will actually increase, but the compliance</p> <p>15 decreases.</p> <p>16 Q. Will toughness decrease when there's oxidative</p> <p>17 degradation?</p> <p>18 A. Yes. The material becomes embrittled.</p> <p>19 Q. And, Doctor, you know what toughness is, don't</p> <p>20 you?</p> <p>21 A. I do.</p> <p>22 Q. And that's the area -- that's the area under</p> <p>23 the curve under a stress-strain?</p> <p>24 A. That's one good measure of toughness, yes.</p>

21 (Pages 78 to 81)

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<p style="text-align: right;">Page 82</p> <p>1 Q. In fact, that's probably the best measure of 2 toughness, isn't it? 3 A. It's a great one, yes. 4 Q. Okay. And that's the one you teach your 5 students at UT? 6 A. I certainly do, yes. 7 Q. Okay. And when a material increases in 8 toughness, what does that tell you about the property, 9 physical properties? 10 A. It tells me it got tougher. 11 Q. And when a material increases in toughness, 12 what does that tell you about whether or not degradation 13 has occurred? 14 A. It would -- it might depend on the material. 15 You can't just make a broad, sweeping statement with 16 every material that it's going to be the same. 17 Q. Okay. What about Prolene? What does that tell 18 you about the toughness of Prolene? 19 A. It's known that when polypropylene oxidatively 20 degrades, it becomes embrittled. So less tough, more 21 brittle. 22 Q. And for Prolene, when -- if Prolene oxidatively 23 degrades, Prolene toughness will decrease; correct? 24 A. Yes.</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. No, sir. My question is: Are you aware of any 2 peer-reviewed literature that shows Prolene has lost 3 molecular weight? 4 A. You mean it's become lower molecular weight 5 after a degradation process? 6 Q. My question is: Are you aware of any 7 peer-reviewed literature that shows Prolene has lost 8 molecular weight specifically? 9 A. Has lost molecular weight due to what? That's 10 what I'm asking. 11 Q. For any reason. 12 A. If one just takes the material and puts it in 13 an extruder and keeps heating and shearing it, it's 14 going to lose molecular weight. 15 Q. Right. But my question is about peer-reviewed 16 literature. Are you aware of any peer-reviewed 17 literature that shows Prolene has lost molecular weight 18 specifically? 19 A. As I sit here, I don't know a paper with 20 Prolene specifically. 21 Q. And are you aware of any studies that shows 22 Prolene has lost molecular weight? 23 A. Again, your question is vague and I don't 24 understand your question.</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. Do you know Dr. Howard Jordi? 2 A. I've heard the name. I don't know him. 3 Q. Do you know if he has ever found a loss of 4 molecular weight in an explant? 5 A. I don't know. 6 Q. We talked about this earlier, and if we did, I 7 apologize. If there is a loss of molecular weight, 8 there is a decrease in toughness; correct? Of Prolene? 9 A. A decrease in molecular weight? 10 Q. If there's a loss of molecular weight in 11 Prolene, there's a decrease in toughness of Prolene; 12 correct? 13 A. Yes, there generally would be a decrease in 14 toughness with decrease in molecular weight, but it's 15 not that simple, because people have tried with 16 ultrahigh molecular weight polymers like polyethylene to 17 get the degree of crystallinity as high as possible 18 through processing tricks, and if you do that, you can 19 actually cause the material to become brittle. So 20 processing plays a role. I'm not trying to be 21 difficult. It's just -- it's more complicated. 22 Q. Doctor, are you aware of any peer-reviewed 23 literature that shows Prolene has lost molecular weight? 24 A. You mean has actually been degraded?</p>	<p style="text-align: right;">Page 85</p> <p>1 Q. My question is, sir: Are you aware of any 2 studies that shows Prolene has specifically lost 3 molecular weight? 4 A. It has become reduced in molecular weight, one 5 average or the other, after some physical encounter? As 6 I sit here, no. 7 Q. And, Doctor, have you ever seen any type of 8 specific molecular weight tests that have been done on 9 Prolene? 10 A. I saw a little bit of GPC data in some of the 11 internal Ethicon documents. 12 Q. And what did it show? 13 A. What they showed in that limited data was 14 marginal changes, small changes, in molecular weight. 15 Q. Doctor, are you aware of any evidence to 16 confirm that these 28 plaintiffs' explants lost 17 molecular weight? 18 A. I have not seen molecular weight data on 19 explants of these patients. 20 Q. And, Doctor, have you seen any evidence to 21 confirm that these 28 patients' explants had a change in 22 the physical properties of their mesh? 23 A. Just back to what I said earlier, 24 polypropylene, including Prolene, undergoes oxidative</p>

22 (Pages 82 to 85)

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<p style="text-align: right;">Page 86</p> <p>1 degradation.</p> <p>2 Q. Doctor, we've talked about antioxidants</p> <p>3 already?</p> <p>4 A. Yes.</p> <p>5 Q. Do you know the antioxidants that are added to</p> <p>6 turn pure polypropylene into Prolene?</p> <p>7 A. Yes. There's several additives that are put in</p> <p>8 there. I've actually got a document here that lists the</p> <p>9 amounts of all of them, but there's Santonox, the</p> <p>10 primary antioxidant, there's calcium stearate, a</p> <p>11 processing aid, and there's a secondary antioxidant. I</p> <p>12 forget the name. It's a long, complicated name. You</p> <p>13 probably wouldn't want to type it.</p> <p>14 Q. Dilauryl thiodipropionate?</p> <p>15 A. That's it. That's it.</p> <p>16 Q. Doctor, do you know the concentration levels of</p> <p>17 these antioxidants?</p> <p>18 A. Again, I would have to --</p> <p>19 Q. Excuse me -- that are -- do you know the</p> <p>20 concentration levels of these antioxidants that are</p> <p>21 added to make polypropylene Prolene?</p> <p>22 A. I could go and review it, but I can't off the</p> <p>23 top of my head remember the exact amount.</p> <p>24 Q. Doctor, have you ever done a TGA analysis to</p>	<p style="text-align: right;">Page 88</p> <p>1 A. No.</p> <p>2 Q. And you've never studied how long the</p> <p>3 antioxidants in Prolene will delay oxidation in vivo;</p> <p>4 correct?</p> <p>5 A. I've seen literature both internal to Ethicon</p> <p>6 and peer-reviewed literature that shows degradation of</p> <p>7 Prolene biomaterials after certain times of implantation</p> <p>8 in the body, but I haven't tested it with my own hands.</p> <p>9 Q. And, Doctor, do you know the step in the</p> <p>10 manufacturing process where these antioxidants are</p> <p>11 added?</p> <p>12 A. Yes. It's during the extrusion process. These</p> <p>13 pellets basically are produced by that process.</p> <p>14 Q. It's your testimony under oath that the pellets</p> <p>15 are produced during the extrusion process?</p> <p>16 A. Well, the polypropylene comes out of the</p> <p>17 reactor, and as I understand it, they then are</p> <p>18 introducing the antioxidant into the material by a</p> <p>19 mixing process, basically.</p> <p>20 Q. So my question is: At what stage of the</p> <p>21 manufacturing process are the antioxidants added?</p> <p>22 A. It's put in before the fibers are actually</p> <p>23 spun. It's in there in the polypropylene.</p> <p>24 Q. Is it put -- is it put before the fibers are</p>
<p style="text-align: right;">Page 87</p> <p>1 determine what antioxidants Prolene contains?</p> <p>2 A. I have not performed TGA on Prolene.</p> <p>3 Q. And, Doctor, have you ever done any type of TGA</p> <p>4 analysis to determine whether or not antioxidants had</p> <p>5 been depleted from Prolene?</p> <p>6 A. I have not.</p> <p>7 Q. You did that for Boston Scientific, didn't you?</p> <p>8 A. Yes.</p> <p>9 Q. Why didn't you do it here?</p> <p>10 A. Because I didn't have the explants.</p> <p>11 Q. That could have been -- you could have done</p> <p>12 that by other means; correct?</p> <p>13 A. One could use an oxidation induction test.</p> <p>14 That's an alternate way.</p> <p>15 Q. And that's something that you had available to</p> <p>16 your lab at Tennessee?</p> <p>17 A. We did, yeah. We could have done that.</p> <p>18 Q. And that's something you didn't do in this</p> <p>19 case; correct?</p> <p>20 A. We didn't.</p> <p>21 Q. Doctor, you've never tested the effect of</p> <p>22 antioxidants -- strike that.</p> <p>23 You've never tested the effect antioxidants</p> <p>24 have in vivo in Ethicon's Prolene, have you?</p>	<p style="text-align: right;">Page 89</p> <p>1 extruded?</p> <p>2 A. Yes, it's in there before the fibers are</p> <p>3 extruded.</p> <p>4 Q. Doctor, you'll agree that these antioxidants</p> <p>5 work in a synergistic manner; correct?</p> <p>6 A. You mean the two that are in? Yeah, it's</p> <p>7 common to use primary and secondary antioxidants.</p> <p>8 Q. But they work in a synergistic manner?</p> <p>9 A. Yes, they do.</p> <p>10 Q. Okay. And, Doctor, do you know the rate at</p> <p>11 which antioxidants from Prolene are depleted?</p> <p>12 A. Based on the literature that shows the</p> <p>13 oxidation of the material, you can certainly tell when</p> <p>14 depletion has occurred, because that's when you start to</p> <p>15 see signs of oxidative degradation.</p> <p>16 Q. Right, but I'm talking about, Doctor, the rate</p> <p>17 that antioxidants of Prolene are depleted.</p> <p>18 A. Under what conditions?</p> <p>19 Q. In vivo.</p> <p>20 A. The exact rate, some actual study of what's</p> <p>21 happening to the concentration over time, I'm not aware</p> <p>22 of.</p> <p>23 Q. And, Doctor, you're not aware of any</p> <p>24 peer-reviewed literature that shows the rate the</p>

23 (Pages 86 to 89)

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<p style="text-align: right;">Page 90</p> <p>1 antioxidants are depleted, are you, in Prolene?</p> <p>2 A. The direct measure of the depletion at the</p> <p>3 surface, which is where the antioxidant does its work,</p> <p>4 I'm not aware of that exact data, that's correct.</p> <p>5 Q. And, Doctor, you've never done any -- you've</p> <p>6 never done any time studies to determine the rate at</p> <p>7 which the antioxidants of Prolene are depleted, have</p> <p>8 you?</p> <p>9 A. We have not tested Prolene for that.</p> <p>10 Q. Doctor, I didn't see anything in your report</p> <p>11 about leaching, or did I miss it?</p> <p>12 A. I did not have anything in there about</p> <p>13 leaching.</p> <p>14 Q. Okay. And if you don't have anything in your</p> <p>15 report, is it fair for me to assume that you have no</p> <p>16 opinions regarding leaching of antioxidants; correct?</p> <p>17 A. Well, certainly antioxidants can be leached out</p> <p>18 of a material.</p> <p>19 Q. But my question is, sir: Are you testifying to</p> <p>20 a reasonable degree of scientific certainty in this</p> <p>21 litigation on whether or not the antioxidants can leach</p> <p>22 out of Prolene?</p> <p>23 A. Antioxidants on the surface can leach out.</p> <p>24 Q. And is that included in your -- is that opinion</p>	<p style="text-align: right;">Page 92</p> <p>1 A. I believe it would, yes.</p> <p>2 Q. And, in fact, formalin is a good solvent;</p> <p>3 correct?</p> <p>4 A. Yes.</p> <p>5 Q. Doctor, do you have any evidence that these 28</p> <p>6 plaintiffs had a loss of antioxidants in their mesh?</p> <p>7 Any data to confirm that their explants lost</p> <p>8 antioxidants?</p> <p>9 A. When you put a material inside the human body,</p> <p>10 you get the foreign body response, and that generates</p> <p>11 strong oxidizing agents, and those oxidizing agents use</p> <p>12 up the antioxidant. The antioxidant's put in there to</p> <p>13 preferentially react with oxidizing species and with</p> <p>14 free radicals.</p> <p>15 Q. Doctor, can you tell us how any of these 28</p> <p>16 plaintiffs' antioxidants -- strike that.</p> <p>17 Can you tell us how any -- strike that.</p> <p>18 Can you tell us the rate at which the</p> <p>19 antioxidants of any of these 28 plaintiffs were</p> <p>20 depleted?</p> <p>21 A. The exact rate, no.</p> <p>22 MR. HUTCHINSON: Can we take a quick break?</p> <p>23 MR. MONSOUR: Yes.</p> <p>24 (Recess from 10:20 a.m. until 10:35 a.m.)</p>
<p style="text-align: right;">Page 91</p> <p>1 included in your report?</p> <p>2 A. No, but we talk about how the antioxidants are</p> <p>3 depleted over time.</p> <p>4 Q. Why are none of your leaching -- strike that.</p> <p>5 Why are none of your opinions regarding</p> <p>6 leaching included in your expert report?</p> <p>7 A. I think leaching is a relatively minor cause of</p> <p>8 depletion as opposed to the antioxidants simply being</p> <p>9 used up doing their job.</p> <p>10 Q. Doctor, my question is: Why did you not</p> <p>11 include any opinions regarding leaching in your expert</p> <p>12 report?</p> <p>13 A. I don't think they're really relevant here.</p> <p>14 The oxidizing agents inside the body react with the</p> <p>15 antioxidants on the surface of the fiber, and that's the</p> <p>16 primary cause for depletion of the antioxidants, and</p> <p>17 then the subsequent oxidative degradation process.</p> <p>18 Q. As a polymer scientist, you're familiar with</p> <p>19 formalin; correct?</p> <p>20 A. Yes.</p> <p>21 Q. And you know that formalin extracts Santonox R;</p> <p>22 correct?</p> <p>23 A. Yes.</p> <p>24 Q. And you know formalin extracts DLTDP; correct?</p>	<p style="text-align: right;">Page 93</p> <p>1 MR. HUTCHINSON: Back on the record.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Doctor, is there anything about the testimony</p> <p>4 you've given me you'd like to change?</p> <p>5 A. No.</p> <p>6 Q. Let's look at the expert report, Exhibit 3.</p> <p>7 A. Okay.</p> <p>8 Q. Page 2. Middle paragraph. It states you have</p> <p>9 developed new biomaterials?</p> <p>10 A. Yes.</p> <p>11 Q. Are they sold to anyone right now, sir?</p> <p>12 A. No. We've got a patent on a new orthopedic</p> <p>13 bone cement.</p> <p>14 Q. Do they have a lifetime warranty?</p> <p>15 A. Well, as I say, we haven't actually made the</p> <p>16 product, but --</p> <p>17 Q. You haven't made the product?</p> <p>18 A. We haven't made the commercial product.</p> <p>19 Q. Okay. Well, but will this commercial product</p> <p>20 have a lifetime warranty?</p> <p>21 A. I don't know.</p> <p>22 Q. Will it have any warranty at all?</p> <p>23 A. I don't know.</p> <p>24 Q. And it's a biomaterial product?</p>

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<p style="text-align: right;">Page 94</p> <p>1 A. It's a biomaterial.</p> <p>2 Q. And what's it used for?</p> <p>3 A. It would be used for hip replacement surgeries,</p> <p>4 knees.</p> <p>5 Q. And sitting here today, sir, do you have any</p> <p>6 plans to give this hip implant that you're creating a</p> <p>7 lifetime warranty?</p> <p>8 A. I have no plans one way or the other.</p> <p>9 Q. You only have one patent; correct?</p> <p>10 A. No.</p> <p>11 Q. I'm looking at the top of page 3. It says "a</p> <p>12 patent," which I think is singular. How many patents do</p> <p>13 you have?</p> <p>14 A. There's a list in here. If you go to my CV,</p> <p>15 it's after the publications. There's a list of patents.</p> <p>16 There's several issued patents there and there's a total</p> <p>17 of 17 things listed in various stages. It's right after</p> <p>18 the publications but before the presentations start.</p> <p>19 MR. MONSOUR: Maybe next time we ought to</p> <p>20 number at the bottom to make it easier. This is</p> <p>21 pretty long.</p> <p>22 THE WITNESS: That would make it easier.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Doctor, none of those patents have anything to</p>	<p style="text-align: right;">Page 96</p> <p>1 oxidize? What do you mean by "foreign body material"?</p> <p>2 Do you mean something that's being implanted in the</p> <p>3 human body?</p> <p>4 Q. Yes.</p> <p>5 A. Maybe Teflon.</p> <p>6 Q. You said "maybe." You don't sound too sure.</p> <p>7 A. I'm not sure. The human body is pretty</p> <p>8 aggressive.</p> <p>9 Q. Yeah. And, in fact, Doctor, sitting here</p> <p>10 today, can you tell us the name of one medical product</p> <p>11 commercially available that will never oxidize in the</p> <p>12 human body?</p> <p>13 A. No.</p> <p>14 Q. Doctor, turning to page 5, at the top, you</p> <p>15 state: "This report focuses on" -- do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. -- "degradation of polypropylene by</p> <p>18 thermo-oxidative processes."</p> <p>19 What do you mean by "thermo"?</p> <p>20 A. Combination of heat combined with oxygen.</p> <p>21 Q. And are you talking about a process of heat</p> <p>22 initiated in the body?</p> <p>23 A. No, it's degradation of polypropylene by</p> <p>24 thermo-oxidative processes and in vivo. So they're two</p>
<p style="text-align: right;">Page 95</p> <p>1 do with pelvic mesh; correct?</p> <p>2 A. Correct.</p> <p>3 Q. And, Doctor, looking at the top of page 3, it</p> <p>4 says: "My work." Are you there with me?</p> <p>5 A. Yes.</p> <p>6 Q. "My work in this area includes development of</p> <p>7 novel bone cements, dental biomaterials, tissue</p> <p>8 engineering, drug delivery systems, surgical sealants,</p> <p>9 and polypropylene pelvic mesh."</p> <p>10 Did I read that correctly?</p> <p>11 A. Yes.</p> <p>12 Q. And, Doctor, what development of polypropylene</p> <p>13 pelvic mesh have you done?</p> <p>14 A. Well, actually, I was referring to the study</p> <p>15 that we did on the materials.</p> <p>16 Q. Okay. So you've never developed polypropylene</p> <p>17 pelvic mesh, have you, sir?</p> <p>18 A. No, not actually developed it.</p> <p>19 Q. Is that a little misleading?</p> <p>20 A. Yeah, I probably was a little clumsy in terms</p> <p>21 of how I phrased it.</p> <p>22 Q. Doctor, are you aware of any foreign body</p> <p>23 material that will never oxidize?</p> <p>24 A. Any foreign body material which will never</p>	<p style="text-align: right;">Page 97</p> <p>1 separate things.</p> <p>2 Q. Doctor, you're not telling the ladies and</p> <p>3 gentlemen of the jury that Prolene oxidizes via thermal</p> <p>4 means; correct?</p> <p>5 A. Well, polypropylene is susceptible to thermal</p> <p>6 oxidative degradation. You heat Prolene up in the</p> <p>7 presence of oxygen and it will degrade.</p> <p>8 Q. Right. But, Doctor, are you offering any</p> <p>9 opinions on Prolene oxidizing in the human body as a</p> <p>10 result of high temperatures?</p> <p>11 A. Not high temperature. In the body, it's</p> <p>12 obviously at body temperature, 37 degrees.</p> <p>13 Q. And, Doctor, have you proven using the</p> <p>14 scientific method that Prolene oxidizes in the body at</p> <p>15 37 degrees C?</p> <p>16 A. We've proven that polypropylene oxidizes inside</p> <p>17 the body at 37 degrees C.</p> <p>18 Q. I understand.</p> <p>19 A. And Ethicon's own scientists have shown that</p> <p>20 polypropylene oxidizes in vivo.</p> <p>21 Q. My question to you, Doctor, is: Have you</p> <p>22 personally proven using the scientific method that</p> <p>23 Prolene oxidizes in vivo at 37 degrees C?</p> <p>24 A. I have not done the experiment with</p>

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<p style="text-align: right;">Page 98</p> <p>1 polypropylene, but as I say, the Ethicon people have, 2 and others have looked at degradation of Prolene 3 implants inside the body. 4 Q. Doctor, turning to page 5, under summary of 5 opinions, No. 1, it discusses the chain scission and 6 diminished mechanical properties, reduced compliance and 7 brittleness. Do you see that? 8 A. Yes. 9 Q. And as a polymer scientist, you know what solid 10 scientific data is, don't you? 11 A. Yes. 12 Q. In fact, you use that in your practice? 13 A. Yes. 14 Q. And using good scientific, solid data is good 15 science; right? 16 A. Yes. 17 Q. And, Doctor, are you aware of any solid 18 scientific data that shows where Prolene has diminished 19 physical properties? 20 A. Yes. 21 Q. What? 22 A. It would be the papers of Costello. 23 Q. Anyone else? 24 A. Those are the primary ones that have looked at</p>	<p style="text-align: right;">Page 100</p> <p>1 A. I am in that document, yes. 2 Q. And, Doctor, you'll agree that only one 3 explanted fiber was tested, would you not? 4 A. It was 5-0 Prolene from Specimen 2. 5 Q. But one explanted fiber was tested; correct? 6 A. They performed tests on one explanted fiber, 7 but there's no indication of how many times that might 8 have been tested. 9 Q. And, Doctor, as a scientist, would you ever 10 rely on one data point in drawing conclusions for a 11 paper that you'd present to the American Chemical 12 Society? 13 A. Well, my point is, they may have actually 14 tested that sample multiple times. 15 Q. But my question to you, Doctor, and listen 16 closely to my question: Would you ever rely, as a 17 scientist, on one data point in drawing a conclusion for 18 a paper that you'd present to the American Chemical 19 Society? 20 A. I would rely on one data point, but I would 21 want more data, and what they show in this paper is 22 there's evidence of other fibers cracking. 23 Q. And, Doctor, did you rule out that the fiber 24 had been damaged by a scalpel? Did you rule that out?</p>
<p style="text-align: right;">Page 99</p> <p>1 Prolene. 2 Q. Right. But, Doctor, I'm asking you for solid 3 scientific data. Other than Costello, are you aware of 4 any solid scientific data that shows Prolene has 5 diminished physical properties? 6 A. There's also data in Ethicon's own studies 7 where in one instance material retained only 54 percent 8 of its initial strength after oxidative degradation. 9 Q. Doctor, you're talking about the 1983 document 10 from Ethicon? 11 A. I'd have to look at it. There's a couple of 12 1983 documents, but that sounds about right. 13 Q. But when we're talking about the suture 14 retained only 54 percent of its original strength, 15 you'll agree that in that study only one explanted fiber 16 was tested? 17 A. I'd have to look at that study to say. 18 Q. Okay. Do you have that study with you? 19 A. I believe I do. 20 What was the number on that one? I'd have to 21 go back to my report and track it down that way. 22 Q. ETH.MESH.15955438? 23 A. Okay. 24 Q. Are you there with me, Doctor?</p>	<p style="text-align: right;">Page 101</p> <p>1 A. You would think that they would not test 2 material that had been damaged by a scalpel. 3 Q. How did you rule that out? 4 A. I don't have the fiber to examine. 5 Q. And you didn't rule that out that the fiber had 6 been damaged by a scalpel, had you? 7 A. Well, I trust that Ethicon hires good 8 scientists who would be careful. 9 Q. Did you rule out the fact that Ethicon's fiber 10 was damaged by a scalpel? 11 A. I have no evidence that it was. 12 Q. If you look at -- going back to your report, on 13 page 5, where we discussed chain scission, chain 14 scission produces carbonyl bands; correct? 15 A. Chain scission in polypropylene accompanies the 16 formation of carbonyl bands. It's not that chain 17 scission produces it, but -- 18 Q. And chain scission in Prolene accompanies the 19 formulation of carbonyl bands; correct? 20 A. Yes. 21 Q. In fact, Doctor, a carbonyl band from oxidation 22 is one of the most intensely absorbing functional groups 23 on FTIR; correct? 24 A. Yes, it's one that's easy to see.</p>

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<p style="text-align: right;">Page 102</p> <p>1 Q. You can't miss it if there's oxidation; is that 2 right? 3 A. If there's oxidation, you'll see it, yes. 4 Q. And, in fact, it's a strong and tall peak on 5 the FTIR spectra; correct? 6 A. Yes. 7 Q. And do you know where oxidized -- strike that. 8 Do you know where on the reciprocal centimeter 9 range there would be a peak for oxidized Prolene? 10 A. Yeah, there's several different oxidized 11 species, but you see them, in general, around 1750, 12 roughly. 13 Q. And, Doctor, have you ever seen any literature 14 that confirms there's a peak at 1740 reciprocal 15 centimeters for oxidized Prolene? 16 A. Yes. 17 Q. And what paper is that? 18 A. Well, it's certainly there in the documents of 19 Ethicon, but I believe it's there also in the Costello 20 paper. 21 Q. Are you aware of any other peer-reviewed 22 literature other than Costello that confirms there's a 23 peak at 1750 reciprocal centimeters for oxidized 24 Prolene?</p>	<p style="text-align: right;">Page 104</p> <p>1 A. Yes. 2 Q. In fact, that was something easy for you to do; 3 correct? 4 A. It is easy, yes. 5 Q. In fact, that's something you could have done; 6 correct? 7 A. Yes. 8 Q. Are you an expert in FTIR? 9 A. I would say I'm quite experienced with it. We 10 use it routinely to characterize polymers that we've 11 made. 12 Q. But do you hold yourself as an expert in FTIR? 13 A. Well, I'm not a person who's specialized in 14 spectroscopy my whole career, but we use it as a tool 15 routinely. 16 Q. Doctor, do you tell the students you teach at 17 UT that you're an expert in FTIR analysis? 18 A. I wouldn't classify myself as an expert. 19 There's certainly people that practice it day in and day 20 out that know more about it than I do. 21 Q. And, Doctor, do you know -- well, by the way, 22 FTIR is a way to confirm oxidation? 23 A. Yes. 24 Q. And do you know where on an FTIR spectra a</p>
<p style="text-align: right;">Page 103</p> <p>1 A. For oxidized Prolene, I think that's the one. 2 Q. Costello is the one you're relying on? 3 A. Yeah. There's actually two Costello papers, 4 yeah. 5 Q. Doctor, have you ever seen carbonyl bands from 6 Prolene after it was implanted in vivo? 7 A. Well, as we just said, I've seen evidence 8 gathered by Ethicon scientists and also from Costello. 9 Q. But outside of the documents that you've 10 reviewed, the internal documents and peer-reviewed 11 literature, Doctor, have you ever seen an FTIR spectra 12 that has a carbonyl band at or around 1750 for oxidized 13 Prolene? 14 A. You mean with my -- something we generated in 15 the lab? 16 Q. Yes, sir. 17 A. No. 18 Q. With your own eyes. 19 A. No, we have not. 20 Q. And, Doctor, have you ever done an FTIR spectra 21 for Prolene? 22 A. For polypropylene, yes. For Prolene, no. 23 Q. Doctor, you had the equipment at your lab at UT 24 to do an FTIR spectra on Prolene, didn't you?</p>	<p style="text-align: right;">Page 105</p> <p>1 functional group for DLTDP shows up? 2 A. There's one that comes in about 1740, in that 3 general vicinity, as well. 4 Q. Doctor, looking on page 5 of your report, it 5 says, No. 2: "The addition of antioxidants to the 6 Prolene polypropylene does not permanently prevent mesh 7 degradation." 8 Do you see that? 9 A. Yes. 10 Q. Doctor, have you proven that using the 11 scientific method? 12 A. Well, polypropylene routinely contains 13 antioxidants. 14 Q. But I'm talking about Prolene. Have you 15 proven, Doctor, that the addition of antioxidants to 16 Prolene does not permanently prevent mesh degradation, 17 by the scientific method? 18 A. It's there in the published peer-reviewed 19 literature and also in the Ethicon documents. As I keep 20 saying, we have not done the experiments on Prolene. 21 Q. Doctor, what's the longest time that you're 22 aware of where Prolene material has been used in the 23 body? 24 A. There were some seven-year studies I saw from</p>

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<p style="text-align: right;">Page 106</p> <p>1 Ethicon.</p> <p>2 Q. I'm talking about used in the body in a</p> <p>3 clinical sense.</p> <p>4 A. I'd have to go back to some of the papers to</p> <p>5 see, really, what the longest time was, but periods of</p> <p>6 years.</p> <p>7 Q. Doctor, look at page 11 for me, please. Down</p> <p>8 at the middle, you have a sentence regarding -- that</p> <p>9 starts with "macrophages." Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. Doctor, do you know what amount of peroxides</p> <p>12 are secreted in the body?</p> <p>13 A. I don't know the exact amount.</p> <p>14 Q. Do you know the amount of acids that are</p> <p>15 secreted in the body?</p> <p>16 A. Exact amounts, no.</p> <p>17 Q. What about the amount of enzymes?</p> <p>18 A. Exact amounts, no.</p> <p>19 Q. Doctor, have you ever studied the amount of</p> <p>20 peroxides, acids, or enzymes that are secreted in the</p> <p>21 body?</p> <p>22 A. I have not.</p> <p>23 Q. Can you quantify the concentration of reactive</p> <p>24 oxygen species produced by microphages?</p>	<p style="text-align: right;">Page 108</p> <p>1 acids, or enzymes to determine if it oxidizes?</p> <p>2 A. I have not.</p> <p>3 Q. Doctor, the amount of reactive oxygen species</p> <p>4 in the body, how does that compare to 30 percent</p> <p>5 hydrogen peroxide?</p> <p>6 A. I'm not sure.</p> <p>7 Q. Certainly, Doctor, you would expect that the</p> <p>8 amount of reactive oxygen species in the body is going</p> <p>9 to be much lower than 30 percent hydrogen peroxide,</p> <p>10 wouldn't you?</p> <p>11 A. 30 percent hydrogen peroxide is a pretty high</p> <p>12 concentration.</p> <p>13 Q. And that's a high enough concentration that you</p> <p>14 would expect something to happen to a material; correct?</p> <p>15 A. It depends on the material and the conditions</p> <p>16 under which it's exposed. If you look inside the human</p> <p>17 body, you have not only hydrogen peroxide being</p> <p>18 generated by this foreign body reaction, but you also</p> <p>19 have oxidative enzymes. So catalysts can accelerate the</p> <p>20 process even if the concentration of the peroxide is</p> <p>21 lower. And there are also other highly reactive</p> <p>22 species, like hypochlorous acid, that are generated by</p> <p>23 this process.</p> <p>24 Q. And, Doctor, do you have any idea how much</p>
<p style="text-align: right;">Page 107</p> <p>1 A. It might be available in the literature if I</p> <p>2 would go and look for it. I suspect it is.</p> <p>3 Q. Can you quantify it, Doctor?</p> <p>4 A. As I sit here, no.</p> <p>5 Q. Have you ever looked for any type of</p> <p>6 quantification of reactive oxygen species produced by</p> <p>7 macrophages?</p> <p>8 A. I have not tried to quantify it, no.</p> <p>9 Q. Doctor, are you aware, sitting here today, of</p> <p>10 any peer-reviewed literature where that's been</p> <p>11 quantified?</p> <p>12 A. I am not, as I sit here, but it may very well</p> <p>13 be there. I suspect it is.</p> <p>14 Q. And when we talk about the concentration of</p> <p>15 reactive oxygen species produced by macrophages, you'd</p> <p>16 be guessing at the amount of how much is produced by the</p> <p>17 body; correct?</p> <p>18 A. As I've said, I don't know the exact amount.</p> <p>19 Q. Okay. Do you have -- do you have any idea?</p> <p>20 A. I can't give you a hard number, no.</p> <p>21 Q. Can you give me a best guess?</p> <p>22 A. I'm not here to guess.</p> <p>23 Q. Doctor, have you ever exposed Prolene to what</p> <p>24 you would consider an appropriate amount of peroxides,</p>	<p style="text-align: right;">Page 109</p> <p>1 hypochlorous acid is found in the body in vivo?</p> <p>2 A. I can't quantify it.</p> <p>3 Q. And, Doctor, are you aware of any literature</p> <p>4 whatsoever that quantifies the amount of hypochlorous</p> <p>5 acid in the body?</p> <p>6 A. As I sit here, I'm not sure of it, but I might</p> <p>7 be able to quantify it.</p> <p>8 Q. Have you ever looked for any literature,</p> <p>9 Doctor, before today's deposition, that quantifies the</p> <p>10 amount of hypochlorous acid found in the body?</p> <p>11 A. I have not set out to try to quantify it.</p> <p>12 Q. And have you ever looked in the literature to</p> <p>13 determine how much hydrogen peroxide is found in the</p> <p>14 body, the concentration level?</p> <p>15 A. Again, as I've already said, I haven't tried to</p> <p>16 quantify it.</p> <p>17 Q. Thank you. And, Doctor, these reactive oxygen</p> <p>18 species that you're discussing on page 11 of your</p> <p>19 report, are those stronger than nitric acid?</p> <p>20 A. Certainly under the conditions where there are</p> <p>21 these enzymes present, these oxidative enzymes, they can</p> <p>22 be very potent.</p> <p>23 Q. Doctor, do you have any opinion regarding how</p> <p>24 much hydrogen peroxide would cause Prolene to oxidize?</p>

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<p style="text-align: right;">Page 110</p> <p>1 A. Inside the body, or without?</p> <p>2 Q. Inside the body.</p> <p>3 A. I'm not sure what the minimum level is.</p> <p>4 Q. Do you have any opinion regarding how much</p> <p>5 hydrogen peroxide would cause Prolene to oxidize outside</p> <p>6 the body?</p> <p>7 A. Well, I could go to the study that the Ethicon</p> <p>8 scientists carried out.</p> <p>9 Q. Before we do that, do you have an opinion?</p> <p>10 A. Could you be more specific?</p> <p>11 Q. Well, do you have an opinion about how much</p> <p>12 hydrogen peroxide it takes to oxidize Prolene outside</p> <p>13 the body?</p> <p>14 A. It depends on the exact conditions. 30 percent</p> <p>15 hydrogen peroxide, under the conditions Ethicon used,</p> <p>16 wasn't enough.</p> <p>17 Q. It was not enough?</p> <p>18 A. Over the time period that they carried out the</p> <p>19 experiment.</p> <p>20 Q. And you're talking about the November 5, 1984,</p> <p>21 memo?</p> <p>22 A. Yes, I think so.</p> <p>23 (Mays Exhibit No. 4 was marked for</p> <p>24 identification.)</p>	<p style="text-align: right;">Page 112</p> <p>1 the laboratory, but it's hydrogen peroxide and other</p> <p>2 oxidizing agents generated in vivo where there's also</p> <p>3 oxidative enzymes present.</p> <p>4 In fact, if we continue on page 3 to the next</p> <p>5 paragraph in this same article, it says: "Infrared</p> <p>6 spectroscopic examination of Prolene explants, however,</p> <p>7 do show the presence of oxidative end products. While</p> <p>8 the combination of a proportionally small but severely</p> <p>9 oxidized surface and" --</p> <p>10 Q. Doctor, I'm not going to --</p> <p>11 MR. MONSOUR: Let him finish.</p> <p>12 A. -- yeah -- "a small but severely oxidized</p> <p>13 surface and an unaffected core has not been duplicated</p> <p>14 in laboratory oxidation studies, the possibility of a</p> <p>15 highly specific in vivo oxidation process remains. The</p> <p>16 kinetic features of such a process may deviate from</p> <p>17 conventional oxidation and would be difficult to predict</p> <p>18 or duplicate in an artificial environment."</p> <p>19 Q. Doctor, my question to you is: Is hydrogen</p> <p>20 peroxide in a lab different than hydrogen peroxide in</p> <p>21 the body?</p> <p>22 A. Yes, because inside the body it's not just</p> <p>23 hydrogen peroxide.</p> <p>24 Q. I understand that, but --</p>
<p style="text-align: right;">Page 111</p> <p>1 BY MR. HUTCHINSON:</p> <p>2 Q. We'll mark it as Exhibit 4. This is a document</p> <p>3 that you received before you rendered your opinions; is</p> <p>4 that right?</p> <p>5 A. Yes.</p> <p>6 Q. And, in fact, you relied upon this document in</p> <p>7 reaching your opinions, didn't you, sir?</p> <p>8 A. Yes.</p> <p>9 Q. And there at the top, on page 3, it states:</p> <p>10 "Prolene sutures in 30 percent hydrogen peroxide</p> <p>11 solution after a year's time at room temperature do not</p> <p>12 produce visible surface cracking on any of the fibers."</p> <p>13 Did I read that correctly?</p> <p>14 A. Yes.</p> <p>15 Q. And, in fact, Doctor, this shows that Prolene</p> <p>16 is exposed to 30 percent hydrogen peroxide for a year</p> <p>17 and didn't produce visible surface cracks; is that</p> <p>18 right?</p> <p>19 A. That's what it says.</p> <p>20 Q. Sir, how do you account for the fact -- strike</p> <p>21 that.</p> <p>22 How do you account for that in reaching your</p> <p>23 conclusion that hydrogen peroxide oxidizes Prolene?</p> <p>24 A. As I said before, it's not hydrogen peroxide in</p>	<p style="text-align: right;">Page 113</p> <p>1 A. It's other things.</p> <p>2 Q. Let's focus on hydrogen peroxide first.</p> <p>3 A. Yes, sir.</p> <p>4 Q. Hydrogen peroxide is hydrogen peroxide is</p> <p>5 hydrogen peroxide, regardless of the environment;</p> <p>6 correct?</p> <p>7 A. H2O2, yes.</p> <p>8 Q. Thank you. Doctor, can you explain why the</p> <p>9 30 percent hydrogen peroxide ate away the cap of the</p> <p>10 vial?</p> <p>11 A. It was a material that was more susceptible to</p> <p>12 degradation.</p> <p>13 Q. And, Doctor, the cap of the vial was Bakelite;</p> <p>14 correct? Top paragraph.</p> <p>15 A. Yes.</p> <p>16 Q. And, Doctor, do you know what Bakelite --</p> <p>17 strike that.</p> <p>18 Do you know what a Bakelite cap is made of?</p> <p>19 A. I think it's some sort of phenolic resin, is it</p> <p>20 not?</p> <p>21 Q. And, Doctor, can you explain why the hydrogen</p> <p>22 peroxide solution ate away the cap of the vial but did</p> <p>23 not produce visible cracks in the Prolene?</p> <p>24 A. Because it's chemically different and it's a</p>

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<p style="text-align: right;">Page 114</p> <p>1 material that's even more susceptible to oxidative 2 degradation by hydrogen peroxide than is the Prolene. 3 Q. And, Doctor, let's look at page 11. 4 MR. MONSOUR: Of the report or of the document? 5 MR. HUTCHINSON: I'm sorry. Of the report. My 6 bad. 7 Q. You write in the third paragraph: "Degradation 8 starts at the surface of the implant where it's in 9 contact with its surroundings." 10 Do you see that? 11 A. Where are we now? 12 Q. Page 11. Third paragraph. Or, actually, it's 13 the first paragraph under "effect of polypropylene 14 degradation." 15 A. I see it, uh-huh. 16 Q. And, Doctor, you write: "Degradation starts at 17 the surface of the implant." 18 Do you see that? 19 A. Yes. 20 Q. And if this occurs with Prolene, you would 21 expect to see a reduction in physical properties? 22 A. Yes, once the degradation proceeds to some 23 level, you would see a change in the physical properties 24 of the material.</p>	<p style="text-align: right;">Page 116</p> <p>1 designed to protect Prolene from attack." 2 Do you see that? 3 A. I do. 4 Q. And, Doctor, if that's true, how do you account 5 for the fact that Prolene sutures have been used since 6 the 1960s? 7 A. Well, they can be used and they can have some 8 degradation, but as we said earlier, the suture, it just 9 has to hold a wound closed and the wound heals around it 10 and it's basically done its job. It can have cracking 11 in it, and it can stiffen, and that's okay. 12 That's different from a pelvic mesh where the 13 mesh has to be flexible to move with the soft tissue. 14 Q. The attack that you reference is by reactive 15 oxygen species; correct? 16 A. Yes. 17 Q. And reactive oxygen species, they possess a 18 free radical? 19 A. They generate radicals, yes. 20 Q. And -- well, but they possess a free radical, 21 don't they, sir? 22 A. Well, if you consider hydrogen peroxide to be a 23 reactive oxygen species, it's H2O2, it does not have a 24 radical in there, but if you heat it up or expose it to</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. Okay. And you'd never expect to see an 2 increase in physical properties with degradation? 3 A. Certain properties could be improved with 4 oxidation. 5 Q. What properties -- what physical properties 6 would be improved with oxidative degradation occurring 7 in the body? 8 A. It might improve solvent resistance. It might 9 improve something else. I just hate to say never. 10 Q. I understand that, but my question to you is, 11 Doctor: Would you ever expect to see an increase in 12 physical properties if a material is degraded 13 oxidatively in vivo? 14 A. For example, with Prolene, you see an 15 improvement in modulus. If you're looking for 16 stiffness, you can stiffen the material by an oxidative 17 degradation process. 18 Q. Doctor, let's look on page 13 of your report. 19 At the very bottom, it states -- well, at the bottom of 20 page 13, you discuss Santonox R and DLTDP. Do you see 21 that? 22 A. Yes, I do. 23 Q. And at the bottom of 13, you say: "Neither of 24 these antioxidants," i.e., Santonox R or DLTDP," is</p>	<p style="text-align: right;">Page 117</p> <p>1 appropriate conditions, then it can form free radicals. 2 Q. Well, a reactive oxygen species has a nonbonded 3 electron that wants to bond to something, doesn't it? 4 A. Well, you could consider it to be a reactive 5 oxygen species, even that H2O2, in its molecular form. 6 It's still a reactive oxygen-containing species. 7 Q. Right, but a free radical is not bonded, is it, 8 sir? 9 A. A free radical has an unpaired electron, that's 10 right. 11 Q. Okay. And an unpaired electron means that it's 12 not bonded; correct? 13 A. That's right. 14 Q. Okay. And a free radical is a free radical is 15 a free radical, regardless of the origin? 16 A. Well, there are all sorts of different free 17 radicals with all different sorts of reactivity or 18 stability, depending on how you want to look at it. 19 They're not all the same. 20 Q. Is there any difference between a free radical 21 formed in the body and one that's formed in the 22 extrusion or heating process? 23 A. There may well be different things that are 24 formed.</p>

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<p style="text-align: right;">Page 118</p> <p>1 Q. Santonox R and DLTDP are free radical 2 scavengers, aren't they? 3 A. Actually, Santonox preferentially reacts with 4 the oxygen-containing species, but the -- what's it 5 called? -- 6 Q. DLTDP? 7 A. -- that guy is a free radical scavenger. 8 Q. Okay. And it's your testimony that Santonox R 9 is not a free radical scavenger? 10 A. Well, it primarily works by reacting with the 11 oxygen itself. 12 Q. But is it a free radical scavenger, sir? 13 A. At some level, yes. 14 Q. Thank you. And, in fact, that's their job is 15 to remove free radicals that want to bond? 16 A. That's certainly part of their job, yes. 17 Q. And, at a minimum, you'll agree that Santonox R 18 and DLTDP are designed to retard the formation of free 19 radicals? 20 A. Yes. 21 Q. Okay. And, Doctor, do you have a solution for 22 what types of antioxidants should be used to prevent 23 oxidation in the pelvic floor region? 24 A. I simply don't think that there's adequate</p>	<p style="text-align: right;">Page 120</p> <p>1 oxidative degradation inside the body for the lifetime 2 of an implant. 3 Q. Okay. And how much antioxidants should be put 4 in there to prevent lifetime degradation of an implant? 5 A. There would have to be more. 6 Q. Can you tell us that concentration level? 7 A. I cannot tell you the exact concentration 8 level. One would have to do experiments. 9 Q. And you've not done any of those experiments; 10 correct? 11 A. No, and I don't think Ethicon has either. 12 Q. And if you'd look at page 14 of your report, 13 you cite Liebert? 14 A. Yes. 15 Q. I presume you'd consider Liebert authoritative? 16 A. Yes. 17 Q. And you'll agree that there was no loss of 18 molecular weight with the fiber that Liebert studied 19 that had antioxidants in it? 20 A. Not under the conditions that they carried out 21 the study. 22 Q. Thank you. And, Doctor, you will also agree 23 that the fiber with antioxidants showed no changes in 24 molecular weight?</p>
<p style="text-align: right;">Page 119</p> <p>1 antioxidants out there to render polypropylene 2 permanently stable to oxidative effects inside the body. 3 Q. And, Doctor, do you have an alternative to 4 DLTDP or Santonox R to prevent oxidizing degradation? 5 A. I don't think there's an antioxidant package 6 out that that will do it, as I just said. You can try 7 to add more, but the antioxidants themselves have 8 toxicity issues. 9 Q. And, Doctor, you have no opinion on the 10 concentration levels of Santonox R or DLTDP, do you? 11 A. Well, in general, if you're trying to prevent 12 the oxidative degradation, more is better, but the human 13 body, the fact that it's to be used inside the body and 14 the fact that the Santonox and the DLTDP come with MSDS 15 sheets that have cautions regarding their use in the 16 body, might cause one not to put as much as possible in 17 there. 18 Q. Do you have an opinion, sir, on whether or not 19 Ethicon's Prolene material has too much or too little 20 Santonox R and DLTDP as far as concentration levels are 21 concerned? 22 A. Too much or too little for what? 23 Q. To prevent oxidation. 24 A. There's not enough in there to prevent</p>	<p style="text-align: right;">Page 121</p> <p>1 A. They did observe changes in molecular weight. 2 Q. Of the fiber with antioxidants? 3 A. But that was for a fiber without antioxidants 4 in there. 5 Q. But for the fiber with antioxidants, there was 6 no change in molecular weight; correct? 7 A. They did not detect any, that's correct. 8 Q. Right. And, in fact, sir, the fiber with 9 antioxidants showed no lowering of the glass transition 10 temperature, did it? 11 A. I would have to go back and look at that. 12 Q. Liebert didn't do any cleaning of the fibers, 13 did he? 14 A. I don't recall that Liebert did cleaning. 15 Again, I'd have to look at the paper. 16 Q. Sir, do you know if Liebert even used Prolene? 17 A. As I recall, Liebert was using a Pro-fax 18 polypropylene, and I know Pro-fax pretty well, because 19 that was a Hercules polypropylene. 20 Q. But, Doctor, you can't testify under oath that 21 Liebert used a Prolene product, can you? 22 A. No. 23 Q. Turning to page 15, Jongebloed, we've talked 24 about that; right?</p>

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<p style="text-align: right;">Page 122</p> <p>1 A. Yes.</p> <p>2 Q. Doctor, that's -- it was a suture implanted in</p> <p>3 the eye for six and a half years?</p> <p>4 A. Yes, the first study was.</p> <p>5 Q. And you'll agree that UV light causes</p> <p>6 degradation?</p> <p>7 A. UV light can cause degradation, yes.</p> <p>8 Q. Doctor, do you believe that there were hydrogen</p> <p>9 peroxides in the eye that caused degradation of the</p> <p>10 sutures?</p> <p>11 A. There certainly could have been, yes.</p> <p>12 Q. And you'll agree that the eye is full of</p> <p>13 proteins, wouldn't you?</p> <p>14 A. There's proteins in the eye.</p> <p>15 Q. In fact, that's what builds up on contacts?</p> <p>16 A. Yes.</p> <p>17 Q. That's what you've seen in your work?</p> <p>18 A. Yes.</p> <p>19 Q. The authors didn't do any SEM or FTIR analyses,</p> <p>20 did they?</p> <p>21 A. They did SEM analysis.</p> <p>22 Q. But they didn't do any FTIR, did they?</p> <p>23 A. Again, we could go back and look at the paper.</p> <p>24 I don't recall any.</p>	<p style="text-align: right;">Page 124</p> <p>1 A. Can we look in there?</p> <p>2 Q. Absolutely.</p> <p>3 A. They did carry out a cleaning study.</p> <p>4 Q. My question is, sir: The FTIR analysis in Mary</p> <p>5 did not show a peak at 1740 reciprocal centimeters for</p> <p>6 the DLTDP wavelength; correct?</p> <p>7 A. They measured the absorbance at 1740.</p> <p>8 Q. Yes, sir, but did they recognize that</p> <p>9 wavelength for DLTDP, is my question?</p> <p>10 A. They did not, but they had cleaned the sample,</p> <p>11 and that would remove surface antioxidants. Plus, the</p> <p>12 sutures had been in the body for two years, which would</p> <p>13 also deplete antioxidants present at the surface.</p> <p>14 Q. The authors in Mary didn't compare the</p> <p>15 elongation of Prolene to PVDF, did they?</p> <p>16 A. Compare the elongation of the Prolene and the</p> <p>17 PVDF?</p> <p>18 Q. That's correct.</p> <p>19 A. PVDF? I don't see the comparison.</p> <p>20 Q. Doctor, on page 20 of your expert report,</p> <p>21 there's an SEM photograph?</p> <p>22 A. Yes.</p> <p>23 Q. That's not a -- that's not a Prolene product,</p> <p>24 is it? Top of page 20.</p>
<p style="text-align: right;">Page 123</p> <p>1 Q. Okay. Let's look at -- continuing on page 15,</p> <p>2 at the bottom, you cite the Mary article?</p> <p>3 A. Yes.</p> <p>4 Q. And we've talked about Mary already; is that</p> <p>5 right?</p> <p>6 A. Yes.</p> <p>7 Q. And, Doctor, you'll agree that the authors in</p> <p>8 Mary did not recognize 1740 as a wavelength for DLTDP?</p> <p>9 A. I don't know that, but I have no evidence that</p> <p>10 they explicitly pointed that out.</p> <p>11 Q. Well, did the study -- did the Mary study, sir,</p> <p>12 recognize a 1740 wavelength for DLTDP?</p> <p>13 A. I did not see that called out in there.</p> <p>14 Q. And, in fact, sir, if -- how would you know</p> <p>15 that -- first of all, Prolene has DLTDP in it, doesn't</p> <p>16 it?</p> <p>17 A. Yes, it does.</p> <p>18 Q. And if the Mary article did not have a</p> <p>19 wavelength at 1740 reciprocal centimeters for DLTDP, how</p> <p>20 in the world do you know it's Prolene that they were</p> <p>21 looking at?</p> <p>22 A. I'm not sure I follow you.</p> <p>23 Q. Okay. Well, the FTIR analysis in Mary did not</p> <p>24 show a peak at 1740 reciprocal centimeters?</p>	<p style="text-align: right;">Page 125</p> <p>1 A. Let me see. That's from Lefranc, and that's</p> <p>2 actually from Clave's study, so Clave obtained the</p> <p>3 polypropylene vaginal meshes from a variety of</p> <p>4 manufacturers, and so it could be, but it may not be.</p> <p>5 Q. You can't testify to a reasonable degree of</p> <p>6 scientific certainty that the photograph on the top of</p> <p>7 page 20 is a Prolene product, can you?</p> <p>8 A. No, I can't.</p> <p>9 Q. And, Doctor, on page 21 of your expert report,</p> <p>10 you discuss plasticization?</p> <p>11 A. Yes.</p> <p>12 Q. Do you believe that the Prolene implants on</p> <p>13 these 28 plaintiffs plasticized in vivo?</p> <p>14 A. I believe there is the possibility that some</p> <p>15 plasticization could take place during the process</p> <p>16 inside the body, along with oxidative degradation.</p> <p>17 Q. And, Doctor, is it your opinion to a reasonable</p> <p>18 degree of scientific certainty that the implants in</p> <p>19 these 28 plaintiffs plasticized?</p> <p>20 A. There certainly could have been some</p> <p>21 plasticization of those implants.</p> <p>22 Q. Is that a yes?</p> <p>23 A. Yes, I believe it could happen.</p> <p>24 Q. What effect does plasticization have on the</p>

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<p style="text-align: right;">Page 126</p> <p>1 physical properties of Prolene?</p> <p>2 A. That will actually soften the material.</p> <p>3 Q. And it softens it by a small molecule being</p> <p>4 absorbed into it?</p> <p>5 A. That's correct.</p> <p>6 Q. You've never tested plasticization, have you,</p> <p>7 sir?</p> <p>8 A. Well, I've actually encountered plasticization</p> <p>9 in the course of my career, but I haven't tested it</p> <p>10 with --</p> <p>11 Q. Prolene?</p> <p>12 A. -- directly with Prolene.</p> <p>13 Q. Thank you. And, Doctor, page 25, in the full</p> <p>14 paragraph in the middle, where you discuss the waxy</p> <p>15 scrapings, do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. Now, Bracco, which is one of your references,</p> <p>18 that shows that cyclohexane extracts nonpolar fatty</p> <p>19 acids, correct?</p> <p>20 A. Correct.</p> <p>21 Q. And nonpolar fatty material would be a</p> <p>22 contaminant of Prolene, would it not?</p> <p>23 A. It could be a contaminant in there, yes.</p> <p>24 Q. And the presence of nonpolar fatty material</p>	<p style="text-align: right;">Page 128</p> <p>1 oxidizers. Did I read that correctly?</p> <p>2 A. No, the MSDS sheet states that polypropylene is</p> <p>3 incompatible with strong oxidizers.</p> <p>4 Q. Sorry. You said "incompatible"?</p> <p>5 A. Yeah, polypropylene is incompatible with strong</p> <p>6 oxidizers.</p> <p>7 Q. Do you have that material safety data sheet</p> <p>8 with you, sir?</p> <p>9 A. Yes.</p> <p>10 Q. That's the Sunoco material safety data sheet;</p> <p>11 is that right?</p> <p>12 A. Yes, it's Sunoco. At least I did have it.</p> <p>13 There we go.</p> <p>14 Q. And it states that polypropylene is</p> <p>15 incompatible with strong oxidizers, on page 4? That's</p> <p>16 what you wrote in your report; right?</p> <p>17 A. Yeah, on page 4, it says: "The following</p> <p>18 materials are incompatible with this product."</p> <p>19 Q. And if you -- I'm sorry --</p> <p>20 A. It lists a variety of strong oxidizers.</p> <p>21 Q. Right. And, Doctor, if you look at page 5, it</p> <p>22 says: "No epidemiological studies or case reports</p> <p>23 suggest any serious chronic health hazards from</p> <p>24 long-term exposure to polypropylene."</p>
<p style="text-align: right;">Page 127</p> <p>1 would lower a melting point, would it not, sir?</p> <p>2 A. It would not lower the melting point. It would</p> <p>3 not get into the crystalline region of the material. It</p> <p>4 would get into the amorphous material and lower its</p> <p>5 glass transition temperature.</p> <p>6 Q. Doctor, on page 26 of your expert report, you</p> <p>7 discuss a material safety data sheet. Do you see that?</p> <p>8 A. Okay. We're on page 26 now, at the top. Okay.</p> <p>9 Q. Yes, sir.</p> <p>10 A. Yes.</p> <p>11 Q. And I may have asked you this earlier and I've</p> <p>12 forgotten. Have you ever developed or designed a</p> <p>13 polypropylene product?</p> <p>14 A. I have synthesized polypropylene.</p> <p>15 Q. And what did the -- when you say "synthesized,"</p> <p>16 what did you do?</p> <p>17 A. Made it from small molecule precursors by the</p> <p>18 polymerization process.</p> <p>19 Q. For a medical product?</p> <p>20 A. Not for a medical product.</p> <p>21 Q. For what type of product?</p> <p>22 A. Research. R & D.</p> <p>23 Q. And, Doctor, you state here at the top of page</p> <p>24 26 that the MSDS should not be used with strong</p>	<p style="text-align: right;">Page 129</p> <p>1 Did I read that correctly?</p> <p>2 A. No. Actually, it says: "No epidemiological</p> <p>3 studies or case reports suggest any serious chronic</p> <p>4 health hazards from long-term exposure to polypropylene</p> <p>5 decomposition products below the irritation level."</p> <p>6 Q. Why didn't you quote that in your report,</p> <p>7 Doctor?</p> <p>8 A. Well, I very well could have quoted that.</p> <p>9 Q. Why did you not quote that, Doctor?</p> <p>10 A. My report is basically about oxidative</p> <p>11 degradation of polypropylene.</p> <p>12 (Mays Exhibit No. 5 was marked for</p> <p>13 identification.)</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. I'll hand you what we'll mark as Exhibit 5 to</p> <p>16 your deposition. This is a copy of peer-reviewed</p> <p>17 literature that you're one of five authors on; is that</p> <p>18 right?</p> <p>19 A. Yes.</p> <p>20 Q. And, Doctor, before we start this, let me ask</p> <p>21 you this: If you were going to submit an article to</p> <p>22 your peers at the American Chemical Society about the</p> <p>23 degradation of polyurethane, you'd want to study a</p> <p>24 polyurethane product; right?</p>

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<p style="text-align: right;">Page 130</p> <p>1 A. Yes.</p> <p>2 Q. Okay. None of these products that are</p> <p>3 referenced in the Imel article are Prolene, are they,</p> <p>4 sir?</p> <p>5 A. These particular polypropylenes are isotactic</p> <p>6 polypropylene of the Marlex variety. Prolene is an</p> <p>7 isotactic polypropylene.</p> <p>8 Q. But I'm not talking about the chemistry,</p> <p>9 Doctor. I'm asking you whether or not your study used</p> <p>10 Prolene products. Yes or no?</p> <p>11 A. No, we used polypropylene from Marlex. Marlex</p> <p>12 polypropylene.</p> <p>13 Q. In fact, Doctor, your study did not even</p> <p>14 study -- strike that.</p> <p>15 Your study didn't even discuss Prolene</p> <p>16 products, did it?</p> <p>17 A. We do mention Ethicon products at several</p> <p>18 points in here. If you look on page 1, the last</p> <p>19 paragraph, we're talking about Costello, References 9</p> <p>20 and 10. They studied explanted polypropylene hernia</p> <p>21 meshes from CR Bard and Ethicon.</p> <p>22 Q. I'm not talking about the literature. I'm</p> <p>23 talking about Prolene products.</p> <p>24 A. As I've already said, the polypropylene samples</p>	<p style="text-align: right;">Page 132</p> <p>1 Also, when we examined the materials under the</p> <p>2 SEM, we used EDS. EDS is spectroscopy that detects</p> <p>3 whether certain elements are there. So by looking for</p> <p>4 the presence of oxygen, we could see where oxidation had</p> <p>5 taken place on the fiber. If we saw oxygen and</p> <p>6 nitrogen, the nitrogen would tell us that we could have</p> <p>7 proteins there.</p> <p>8 Q. Doctor, on page 1, the first sentence under</p> <p>9 "introduction" says: "Polypropylene has been used for</p> <p>10 hernia repair since 1958."</p> <p>11 Do you see that?</p> <p>12 A. Yes, sir.</p> <p>13 Q. How do you reconcile the fact that Prolene mesh</p> <p>14 has been used since 1958 in hernia repair with your</p> <p>15 opinions regarding oxidation?</p> <p>16 A. Well, again, as I've said before, I don't</p> <p>17 condemn polypropylene universally as a biomaterial, and</p> <p>18 that includes Prolene polypropylene. It has uses.</p> <p>19 This oxidative degradation is occurring for</p> <p>20 polypropylenes inside the human body, but you can have</p> <p>21 some oxidative degradation in a suture or some oxidative</p> <p>22 degradation in a hernia mesh and not have a problem. I</p> <p>23 think a pelvic mesh, because of how the mesh is supposed</p> <p>24 to function inside the body, it's a different material.</p>
<p style="text-align: right;">Page 131</p> <p>1 that we characterized in this work were explanted Marlex</p> <p>2 samples.</p> <p>3 Q. Doctor, page 1, under the abstract, it says:</p> <p>4 "SEM revealed the formation of transverse cracking on</p> <p>5 the fibers which generally, but with some exceptions,</p> <p>6 increased with implantation time."</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And, Doctor, it's well-known that proteins</p> <p>10 adhere to biomaterials within seconds; is that right?</p> <p>11 A. Yes.</p> <p>12 Q. And, Doctor, what did you do to rule out an</p> <p>13 increased layer of proteins building up over</p> <p>14 implantation time?</p> <p>15 A. Yeah. We did a couple of things. We cleaned</p> <p>16 the materials before we performed the FTIR by using a</p> <p>17 bleach solution. That's the ASTM protocol for cleaning</p> <p>18 up the material.</p> <p>19 Also, that's what was done by Dr. Gajanan, I</p> <p>20 guess, the gentleman who provided the explanted Prolene</p> <p>21 samples to Ethicon scientists that they then studied</p> <p>22 with FTIR.</p> <p>23 So we cleaned the materials up to remove the</p> <p>24 tissue, the proteins that were on there.</p>	<p style="text-align: right;">Page 133</p> <p>1 Q. And, Doctor, on page 132 you cite Lefranc;</p> <p>2 correct?</p> <p>3 A. I'm sorry. On page --</p> <p>4 Q. 132.</p> <p>5 A. Yes.</p> <p>6 Yes, I see that now.</p> <p>7 Q. Lefranc didn't do any testing, did he?</p> <p>8 A. He did not.</p> <p>9 Q. He just recited the literature that was out</p> <p>10 there?</p> <p>11 A. It's a review article, basically.</p> <p>12 Q. And, Doctor, page 134 states that the samples</p> <p>13 were preserved in glass jars of formalin?</p> <p>14 A. Yes.</p> <p>15 Q. And this is where you're talking about the 11</p> <p>16 explants of Boston Scientific patients?</p> <p>17 A. Yes.</p> <p>18 Q. And do you know how long these explants were</p> <p>19 preserved in formalin?</p> <p>20 A. I can't recall as I sit here. I think I did</p> <p>21 see that information at some point.</p> <p>22 Q. And, Doctor, you'll agree that the explants had</p> <p>23 protein on them before they were put in the glass jars</p> <p>24 of formalin?</p>

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<p style="text-align: right;">Page 134</p> <p>1 A. Yes.</p> <p>2 Q. And, Doctor, did you consider the chemical</p> <p>3 reaction between formalin and protein in its formation</p> <p>4 of a new polymer?</p> <p>5 A. No, we basically removed the tissue that was on</p> <p>6 there with the bleach treatment.</p> <p>7 Q. Doctor, what effect does formalin have on</p> <p>8 tissue?</p> <p>9 A. The detailed interaction between formalin and</p> <p>10 tissue I'm not familiar with.</p> <p>11 Q. And, Doctor, you'll agree that formaldehyde, or</p> <p>12 formalin -- strike that.</p> <p>13 You'll agree that formalin and proteins</p> <p>14 crosslink to form a new polymer?</p> <p>15 A. I don't know that.</p> <p>16 Q. And, Doctor, do you know whether or not</p> <p>17 formalin and protein create a polymer that acts as a</p> <p>18 hard casing around the fiber?</p> <p>19 A. We saw absolutely no evidence to support that.</p> <p>20 In fact, we have strong evidence to shoot down that</p> <p>21 theory. We simply did not see that.</p> <p>22 Q. And, Doctor, you'll agree that formaldehyde and</p> <p>23 proteins chemically bond to form a new polymer?</p> <p>24 A. I don't see any evidence of that happening in</p>	<p style="text-align: right;">Page 136</p> <p>1 Q. And you would agree that formaldehyde is a</p> <p>2 fixation agent, wouldn't you?</p> <p>3 A. Yes, I would agree with that.</p> <p>4 Q. All right. And formaldehyde, if it fixes</p> <p>5 something on a slide, that means that it makes that</p> <p>6 biological material hard; correct?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. Doctor, if you look at page 134, you</p> <p>9 discuss the cleaning of these explanted specimens. Do</p> <p>10 you see that? Middle of page 134.</p> <p>11 A. Yes, I see that now.</p> <p>12 Q. And you followed ISO 12891?</p> <p>13 A. Yes.</p> <p>14 Q. And that's not a protocol for cleaning</p> <p>15 polypropylene, is it?</p> <p>16 A. It's a protocol for cleaning polyethylene. I</p> <p>17 looked for an ASTM or ISO protocol for cleaning</p> <p>18 polypropylene, and I couldn't find one. And</p> <p>19 polypropylene is chemically very similar to</p> <p>20 polyethylene.</p> <p>21 Also, I'll add, this is the same method that</p> <p>22 Professor Gajanan, or however his name is pronounced,</p> <p>23 used when he had Prolene explanted samples. He cleaned</p> <p>24 them with the same bleach treatment before he provided</p>
<p style="text-align: right;">Page 135</p> <p>1 this case, so I don't agree.</p> <p>2 Q. I'm asking you as a materials scientist. Is it</p> <p>3 your opinion that formaldehyde and proteins do not</p> <p>4 chemically bond to form a new polymer?</p> <p>5 A. I don't know of a situation where that occurs.</p> <p>6 You'd have to show me the literature.</p> <p>7 Q. Doctor, can you draw out the chemical structure</p> <p>8 of a polymer?</p> <p>9 A. Yes.</p> <p>10 Q. Can you draw out the chemical structure of a</p> <p>11 formaldehyde and protein polymer?</p> <p>12 A. I'm not really sure how that interaction would</p> <p>13 occur. It would depend on what kind of protein you're</p> <p>14 talking about and what kind of functional groups were</p> <p>15 present on it.</p> <p>16 Q. Doctor, if you look on page 134 -- well, before</p> <p>17 we move there, Doctor, you will agree that formaldehyde</p> <p>18 fixes tissue; correct?</p> <p>19 A. Yes, I've heard that said, yes.</p> <p>20 Q. In fact, you'll agree that formaldehyde makes</p> <p>21 tissue hard enough so that it could be sliced in the</p> <p>22 microtoming process when creating histology slides;</p> <p>23 you'll agree with that?</p> <p>24 A. Yes, I'll agree with that.</p>	<p style="text-align: right;">Page 137</p> <p>1 them to Dr. Buckley of Ethicon.</p> <p>2 Q. Doctor, are you aware of any ISO protocol</p> <p>3 specifically for cleaning polypropylene or Prolene?</p> <p>4 A. I was not able to find one for polypropylene or</p> <p>5 Prolene.</p> <p>6 Q. And, Doctor, are you aware of any protocol</p> <p>7 whatsoever to remove a protein-formaldehyde polymer?</p> <p>8 A. I haven't explicitly looked for it, but when we</p> <p>9 did our SEM with EDS, we found clean regions with only</p> <p>10 carbon and oxygen, no protein present on the material.</p> <p>11 Q. Doctor, you only did one cycle of cleaning;</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. And you only did 24 hours?</p> <p>15 A. Yes, that's correct.</p> <p>16 Q. Why did you choose 24 hours?</p> <p>17 A. Because it was standard protocol. It's what we</p> <p>18 saw in the ISO standard. It's what we saw that others</p> <p>19 had used in the literature when they cleaned up</p> <p>20 polypropylene explants.</p> <p>21 Q. And you only used sodium hypochlorite and not</p> <p>22 an enzyme; correct?</p> <p>23 A. That's correct.</p> <p>24 Q. Why didn't you use an enzyme?</p>

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<p style="text-align: right;">Page 138</p> <p>1 A. Because this seemed to be the best protocol to 2 use. 3 Q. Doctor, did this protocol clean 100 percent of 4 the biological residue off the fibers? 5 A. As I keep saying, our SEM with EDS can tell us 6 where clean regions are and where they're not. There 7 were regions which were not completely clean, that's 8 correct. 9 Q. And, Doctor, you followed extensively by 10 rinsing? 11 A. Yes. 12 Q. With water? 13 A. Yes. 14 Q. What was the temperature of the water? 15 A. Room temperature. 16 Q. Why wasn't that included in your report? 17 A. Didn't seem relevant. You can't include 18 everything in the report. 19 Q. Did you do any sonication? 20 A. We did not sonicate. 21 Q. Did you use distilled water? 22 A. Yes. 23 Q. Was the water changed out? 24 A. Yes.</p>	<p style="text-align: right;">Page 140</p> <p>1 look at the polypropylene with no oxidation, just as it 2 comes out of the package. 3 Q. Doctor, are you aware that you can go to the 4 library and get the spectra of polypropylene without 5 having to do a spectra? 6 A. Of course we know that. 7 Q. And, Doctor, were FTIRs done before the 8 cleaning process to confirm the presence of proteins? 9 A. We did not. 10 Q. And, Doctor, why not? 11 A. Well, it was clear just visually that protein 12 was on there. 13 Q. And, Doctor, were FTIRs done after the cleaning 14 process to confirm the complete removal of protein? 15 A. Yes, FTIRs were run. 16 Q. And, Doctor, were FTIRs done after the cleaning 17 process to confirm that you were analyzing completely 18 clean polypropylene fibers? 19 A. FTIR was done on the clean fibers. We used the 20 SEM with EDS to look at the materials, and we could see 21 that we had done a very good job of cleaning, although 22 we could in some instances find regions where there was 23 still some tissue there. 24 Q. Doctor, is this the only cleaning process that</p>
<p style="text-align: right;">Page 139</p> <p>1 Q. Why wasn't that included in the report? 2 A. Again, when you're publishing a peer-reviewed 3 paper, you can't include every single detail. 4 Q. Was the water tested at all, sir? 5 A. We used deionized water. 6 Q. Okay. But my question is: Was the water 7 tested? 8 A. We have a conductivity meter connected to it, 9 and it has to pass a certain standard for deionization. 10 Q. Was the water tested, sir, to determine if any 11 proteins were removed? 12 A. No, we did not. 13 Q. Was the water tested, sir, to determine if any 14 polypropylene was removed? 15 A. No. 16 Q. Doctor, what FTIRs -- I'm sorry. Strike that. 17 Were FTIRs done on pristine polypropylene? 18 A. Yes. 19 Q. And that was done to determine what the spectra 20 looks like? 21 A. Yes. 22 Q. Why did y'all do FTIRs on pristine 23 polypropylene? 24 A. Because we wanted the baseline. We wanted to</p>	<p style="text-align: right;">Page 141</p> <p>1 you used to remove the protein-formaldehyde polymer? 2 A. Yes, this is the process we used. 3 Q. And, Doctor, sitting here today, is this the 4 first time you've ever heard of the formation of a 5 protein-formaldehyde polymer when those two agents 6 interact? 7 A. I'm not familiar with the exact structure of 8 what's being formed there. I know you use formaldehyde 9 and formalin to fix tissue. 10 Q. My question, though, is: Sitting here today, 11 is this the first time that you've ever heard of the 12 formation of a protein and formaldehyde polymer? 13 A. I'm not familiar with what you're referring to 14 there. 15 Q. All right. But my question is: Today, 16 March 2, 2016, is this the first time that you've ever 17 heard of the formation of a protein-formaldehyde 18 polymer? 19 A. Yes. 20 Q. And, Doctor, you can't testify to a reasonable 21 degree of scientific certainty that all the protein was 22 removed from these fibers, can you? 23 A. Well, it's all summarized in our report here. 24 We did see some regions that contained biological tissue</p>

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<p style="text-align: right;">Page 142</p> <p>1 on the material even after the cleaning process, but we 2 observed a lot of areas where there was damaged surface 3 of the fiber and we only saw carbon and oxygen present. 4 Q. And, Doctor, for the biological tissue that was 5 present, that was on the mesh explants; right? 6 A. Yes. 7 Q. And you put those mesh explants into a vacuum, 8 didn't you? 9 A. Yes. 10 Q. And, in fact, you put them into a vacuum oven, 11 didn't you? 12 A. Yes. 13 Q. And how long were they put into the vacuum 14 oven? 15 A. They were in that vacuum oven overnight. 16 Q. At what temperature were they in the vacuum 17 oven? 18 A. At room temperature, as it indicates on page 19 134. 20 Q. But the purpose of putting them in a vacuum 21 oven was to dry them; correct? 22 A. Correct. 23 Q. And that would have dried any type of 24 protein-formaldehyde polymer; correct?</p>	<p style="text-align: right;">Page 144</p> <p>1 A. That's correct. 2 Q. And, in fact, a formaldehyde-protein polymer 3 would be a compound, wouldn't it? 4 A. It would. 5 Q. And it wouldn't be detected by EDS, would it? 6 A. Well, it would have nitrogen in there because 7 that's always in proteins, and it would have carbon in 8 there, and it would have oxygen in there. 9 Q. But, in fact, sir, nitrogen is the hardest 10 thing to find on an EDS, isn't it? 11 A. You can find nitrogen in there. 12 Q. Is it hard to find on EDS, sir? 13 A. No. We found it readily. In the SEM with EDS, 14 we see nitrogen readily. 15 Q. EDS cannot tell you or determine the origin of 16 the element, can it? 17 A. Only that the element's there. 18 Q. Can't tell you where oxygen came from, can it? 19 A. Only that it's there. 20 Q. And if oxygen is present, sir, that means you 21 can be looking at biological material? 22 A. No. If you've got only carbon and oxygen 23 present, that's strongly suggestive of an oxidative 24 process. Also, we see chain cleavage of these</p>
<p style="text-align: right;">Page 143</p> <p>1 A. Yes, it would have dried whatever was there, 2 yes. 3 Q. In fact, it would have dried that 4 protein-formaldehyde fiber -- strike that. 5 It would have dried that formaldehyde-protein 6 polymer on the fiber itself, wouldn't it? 7 A. If it were there, it would have dried it, yes. 8 Q. Doctor, on page 134 of your report -- I'm 9 sorry -- of your article, in the right-hand side, it 10 says: "Previous published work has shown that 11 preservation of explanted samples in formalin did not 12 alter the structure and chemistry." 13 Do you see that? 14 A. Yes, I see that. 15 Q. You cite Bracco; correct? 16 A. Yes. 17 Q. In fact, Bracco did not analyze Prolene in his 18 article, did he? 19 A. No. 20 Q. Doctor, on page 135, you discuss EDS; is that 21 right? 22 A. Yes. 23 Q. And EDS, that can only determine elements 24 present, not compounds; right?</p>	<p style="text-align: right;">Page 145</p> <p>1 materials. If you're seeing carbon and oxygen and 2 nitrogen, then you've got biological material. 3 Q. Biological material such as protein contains 4 nitrogen -- I'm sorry -- oxygen, doesn't it? 5 A. Yes, but you would see nitrogen too. 6 Q. Doctor, on page 138, you state, at the bottom: 7 "FTIR shows peaks." 8 Do you see that? 9 A. Let's see. 10 Q. Bottom of page 138. 11 A. On the left side? 12 Q. Yes, sir. 13 A. Okay. I see -- under the discussion? 14 Q. Yep. 15 A. Okay. 16 Q. My question is: How can you distinguish a 17 carbonyl band at 1740 as a result of oxidation and 18 carbonyl bands of ketones, aldehydes, and carboxylic 19 acids in the same range? 20 A. All those peaks show up in that same general 21 regime. 22 Q. And how can you distinguish between them, sir? 23 A. It's relatively difficult to do. 24 Q. Can you distinguish them, sir?</p>

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<p style="text-align: right;">Page 146</p> <p>1 A. I wouldn't say it's impossible, but it's 2 difficult. 3 Q. Can you, as an expert in this litigation, 4 distinguish between those peaks, sir? 5 A. Between the ketone, aldehyde, and carboxylic 6 acid? 7 Q. And oxidation. Can you distinguish between all 8 those peaks on a FTIR spectra? 9 A. Oxidative degradation gives a mixture of 10 products, and all of these contain the carbonyl, and so 11 you have overlapping peaks, so it's hard to resolve them 12 and really tell exactly how much you have of one versus 13 how much you have of the other. 14 Q. My question is: Yes or no, can you distinguish 15 between all these peaks? 16 A. Well, you're going to have to ask me a more 17 clear question that I can really understand. 18 Q. You as an expert in this mesh litigation, can 19 you distinguish between the peaks of oxidation, ketones, 20 aldehydes, or carboxylic acids? 21 A. Well, oxidation gives ketones, aldehydes, and 22 carboxylic acids, so, you know, these are three 23 different oxidative degradation products. 24 Q. I'm sorry, but are you testifying that</p>	<p style="text-align: right;">Page 148</p> <p>1 that's page 141, at Figure 8, what we're seeing in those 2 materials is the fiber cracking, which is a strong sign 3 of oxidation in these materials, and we see that 4 cracking is occurring, you know, after a year in most of 5 the samples. Not all of them, but most of the samples 6 show cracking after a year. So I would say sometime 7 around a year is a good ballpark. 8 Q. But you can't tell us a specific time; correct? 9 A. I can tell you about a year. And it's going to 10 vary from individual to individual, as we talked about 11 earlier. You put the same mesh in two different women 12 and they might respond differently to it. Bodies are 13 different. 14 Q. Doctor, did you review the Ethicon's seven-year 15 dog study? 16 A. Yes, I saw that document. 17 (Mays No. 6 was marked for identification.) 18 BY MR. HUTCHINSON: 19 Q. Hand you what we'll mark as Exhibit 6. And, 20 Doctor, this is a document you relied on; is that right? 21 A. I have seen this document. 22 Q. And you relied on it; correct? 23 A. Yes. 24 Q. Did you notice anything -- what did you notice</p>
<p style="text-align: right;">Page 147</p> <p>1 oxidation causes ketones? 2 A. Yes. 3 Q. Are you testifying that oxidation causes 4 aldehydes? 5 A. Yes. 6 Q. And can you tell, sir, as an expert in this 7 mesh litigation, can you distinguish between the peaks 8 of aldehydes, ketones, or carboxylic acids? 9 A. In the case where they're all being formed and 10 there's a mixture of them, they're overlapping and 11 they're so close together, we didn't even try to 12 deconvolute the peaks and separate out how much of one 13 we have versus the other. 14 Q. Doctor, on page 140: "Antioxidants are 15 preferentially consumed by the oxidizing species." 16 Do you see that? 17 A. Yes. 18 Q. And you can't tell us the rate that is 19 consumed; correct? 20 A. Not the exact, right, no. 21 Q. And, Doctor, can you tell us the point in time, 22 a specific point in time when the oxidizing agents -- 23 I'm sorry -- the antioxidants are consumed? 24 A. Well, if you go over and look on the next page,</p>	<p style="text-align: right;">Page 149</p> <p>1 about the change in mechanical or physical properties of 2 the sutures after they'd been implanted for seven years? 3 A. Again, you'd have to take me back to that. 4 I've seen so many of these documents. 5 Q. Well, Doctor, before we go from that, without 6 looking at -- without looking at the specific data 7 points, what do you recall about the physical properties 8 of the sutures analyzed in the seven-year dog study? 9 A. I don't recall the specifics of the mechanical 10 properties. I just remember that there were indications 11 of oxidation. 12 Q. Did you look, sir, when you reviewed the 13 Burkley dog study, or the seven-year dog study, did you 14 look to see what the results of the physical property 15 testing were? 16 A. I looked at it, but I can't remember at this 17 point as I sit here. 18 Q. Doctor, let's look at page 221. It's 19 ETH.MESH.221. Are you there with me? 20 A. I am there. 21 Q. And we have two computations of molecular 22 weight, weighted average molecular weight, number 23 average molecular weight? 24 A. I think we're looking at different pages.</p>

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<p style="text-align: right;">Page 150</p> <p>1 MR. MONSOUR: I think we've got different 2 pages. My page looks like -- 221 looks like this. 3 Oh, there's a second 221 in the back. We were 4 at 336221. You're at 888221. Okay. Gotcha. 5 MR. HUTCHINSON: Always put the good stuff in 6 the back. 7 MR. MONSOUR: Of course. 8 BY MR. HUTCHINSON: 9 Q. Are you there with me, Doctor? 10 A. Yes, I'm there. 11 Q. Have you seen this particular page with the dog 12 study before today? 13 A. I have seen this before, yes. 14 Q. And did you account for this in reaching your 15 opinions? 16 A. What do you mean by did I "account" for it? 17 Q. Did you consider this particular page 221 when 18 reaching your opinions? 19 A. Yes. 20 Q. And you will agree that the molecular weight 21 differences are very, very small; correct? 22 A. Could you show me which ones you're referring 23 to? 24 Q. The ones discussing current Prolene 4/0 suture</p>	<p style="text-align: right;">Page 152</p> <p>1 from. 2 Q. Well, have you made any efforts to find out 3 more details? 4 A. This is all I've had to date. 5 Q. Have you made any efforts to find out more 6 details, sir? 7 A. I haven't. This is what I had at the time I 8 prepared my report. If they have more data, I would 9 love to see it. 10 Q. But sitting here today, Doctor, with all the 11 data that you have so far, do you have any reason to 12 dispute that Dr. Burkley found no molecular weight 13 degradation? 14 A. Based on what I see in this document, I cannot 15 tell how these values were derived, and what I will say 16 is one has to do the GPC analysis carefully. It's 17 difficult to perform high temperature GPC. We happen to 18 be experts in it. We've had years and years of 19 experience in it. 20 And it's the Z average molecular weight which 21 is most sensitive to degradation, and then the weight 22 average molecular weight is sensitive to degradation as 23 well. The number average molecular weight is not 24 sensitive to degradation.</p>
<p style="text-align: right;">Page 151</p> <p>1 compared to Dog Site 3 and Dog Site 2. Do you see that? 2 Down at the bottom. 3 A. Yes. 4 Q. And what do you notice about the change of 5 molecular weight, Doctor? 6 A. I notice that those are not changing very much. 7 Q. And that was done by GPC; correct? 8 A. Yeah, I would assume so. That's how these 9 values are normally derived. 10 Q. And, in fact, at the bottom, under conclusions, 11 it says: "Comparison of 7-year explants to current 12 Prolene indicate no molecular weight degradation." 13 Did I read that correctly? 14 A. That's what it says. 15 Q. Any reason to dispute that, Doctor? 16 A. Well, I would need to have more details about 17 what they did, because they're also carrying out 18 intrinsic viscosity measurements here, these IV 19 measurements, and it's not clear to me whether they're 20 deriving these MW values from that IV measurement. 21 That's commonly done. 22 And maybe they're getting these number average 23 molecular weights from GPC. I simply don't know. They 24 don't clearly tell me where these values are coming</p>	<p style="text-align: right;">Page 153</p> <p>1 So I don't know enough about where these values 2 came from and the protocol that they use to speculate, 3 and I don't want to speculate. 4 Q. I understand, Doctor, but in all fairness, 5 these values do not support your opinions, do they? 6 A. I don't know enough about these values to be 7 able to say whether they're valid or not. 8 Q. But my question is, Doctor, the values that are 9 on this sheet of paper, do these values support your 10 opinions; yes or no? 11 A. These values here show similar number average 12 molecular weights and similar weight average molecular 13 weights. 14 Q. And do these values, Doctor, support your 15 opinions; yes or no? 16 A. It's impossible for me to say. It really is. 17 I'd have to know more. GPC calibration can change over 18 time. We ran our controls at the same time we were 19 running the explanted studies. I don't know that they 20 did this here. I simply don't have enough data. 21 Q. Doctor, do you have any explanation whatsoever 22 why Dr. Burkley found no loss of molecular weight? 23 A. I don't know whether his conclusion is valid or 24 not. I don't see enough data here for me to make a</p>

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<p style="text-align: right;">Page 154</p> <p>1 decision.</p> <p>2 Q. Do you have any reason to believe that these</p> <p>3 sutures were plasticized?</p> <p>4 A. It is possible that polypropylene does undergo</p> <p>5 some plasticization inside the body.</p> <p>6 Q. And, Doctor, plasticization would improve</p> <p>7 toughness, wouldn't it?</p> <p>8 A. Plasticization would soften the material.</p> <p>9 Q. But it would improve toughness? I'm asking</p> <p>10 about toughness. I'm not asking about softening the</p> <p>11 material. Toughness.</p> <p>12 A. Plasticization at a reasonable level would</p> <p>13 probably improve the toughness of the material.</p> <p>14 Q. Okay. And, Doctor, if toughness of the</p> <p>15 material improves, then we can rule out degradation,</p> <p>16 can't we?</p> <p>17 A. That's not strictly true.</p> <p>18 Q. But, Doctor, as a general rule, you will agree</p> <p>19 that as toughness improves, degradation can be ruled</p> <p>20 out; correct?</p> <p>21 A. I would not make a general statement about</p> <p>22 that. I'd have to consider the specific material.</p> <p>23 Q. Doctor, would that be consistent with the</p> <p>24 principles of polymerization that you used to teach your</p>	<p style="text-align: right;">Page 156</p> <p>1 increased in the third year. But I have no idea how</p> <p>2 many samples were here. Is this a case of a single</p> <p>3 sample?</p> <p>4 Q. Doctor, my question is: Does the data shown on</p> <p>5 page ETH.MESH.183 support your opinions that Prolene</p> <p>6 degrades; yes or no?</p> <p>7 A. It's impossible for me to say.</p> <p>8 Q. You can't answer that question one way or the</p> <p>9 other?</p> <p>10 A. I can't.</p> <p>11 Q. And, Doctor, why can you not answer that</p> <p>12 question one way or the other?</p> <p>13 A. I'd have to know more details about the study.</p> <p>14 Q. And have you made any efforts to find out more</p> <p>15 details about the study?</p> <p>16 A. I have not.</p> <p>17 Q. And, Doctor, you will agree that -- let's look</p> <p>18 at breaking strength. Prolene changed from baseline</p> <p>19 percentage, at Year 7, it decreased 5 percent; correct?</p> <p>20 A. The breaking strength of Prolene, yes.</p> <p>21 Q. Yes. And, in fact, the elongation percentage</p> <p>22 of Prolene increased, from baseline, at Year 7,</p> <p>23 111 percent; correct?</p> <p>24 A. That's what this says, but how many samples?</p>
<p style="text-align: right;">Page 155</p> <p>1 students with at UT?</p> <p>2 A. Plasticization has nothing to do with the</p> <p>3 principles of polymerization.</p> <p>4 Q. Would that be consistent with anything you've</p> <p>5 ever discussed with your students at UT about whether or</p> <p>6 not plasticization can improve toughness?</p> <p>7 A. Plasticization --</p> <p>8 Q. I'm sorry. Strike that.</p> <p>9 Doctor, turn to the last page of the Burkley</p> <p>10 dog study with me, please.</p> <p>11 A. All right.</p> <p>12 Q. Doctor, you will see breaking strength at the</p> <p>13 top. Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. And, by the way, did you ever consider this</p> <p>16 data summary when reaching your opinions, Doctor?</p> <p>17 A. I saw this, so, yeah, I considered it.</p> <p>18 Q. Okay. And do the data shown here on page 183,</p> <p>19 do the data support your opinions that the sutures</p> <p>20 degraded via oxidation?</p> <p>21 A. I see the breaking strength of Prolene staying</p> <p>22 roughly the same. It would be nice to see some error</p> <p>23 bars on this. The elongation percent of Prolene</p> <p>24 actually decreased a bit in Year 2 but seemingly</p>	<p style="text-align: right;">Page 157</p> <p>1 Q. Doctor, let's look at the Young's modulus.</p> <p>2 That's just another name for stiffness, isn't it?</p> <p>3 A. Modulus is related to stiffness of the</p> <p>4 material.</p> <p>5 Q. And stiffness of Prolene at Year 7 decreased</p> <p>6 70 percent; correct?</p> <p>7 A. That's what this says.</p> <p>8 Q. And, Doctor, do you have any reason to believe</p> <p>9 that these values are wrong?</p> <p>10 A. I'm very suspicious of these values, yes.</p> <p>11 Q. Do you have any reason to believe the values</p> <p>12 are wrong, though, Doctor? I'm not asking if you're</p> <p>13 suspicious.</p> <p>14 A. I need more data to really draw a firm</p> <p>15 conclusion.</p> <p>16 Q. You can't tell us if these values are wrong or</p> <p>17 right, can you?</p> <p>18 A. I can tell you I don't believe them.</p> <p>19 Q. And why don't you believe them?</p> <p>20 A. Because they're not realistic.</p> <p>21 Q. Which one is not realistic?</p> <p>22 A. And they're not supported.</p> <p>23 Q. Which one is not realistic? Which figure? Of</p> <p>24 the -5 percent, 111, or 70 --</p>

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<p style="text-align: right;">Page 158</p> <p>1 A. I simply --</p> <p>2 Q. -- hold on just a minute, the court reporter is</p> <p>3 going to get made at us -- which figure do you not</p> <p>4 believe is realistic, Doctor?</p> <p>5 A. I simply cannot place faith in anything in this</p> <p>6 table. I'd have to know more about it.</p> <p>7 Q. Okay. And, Doctor, if you can't place faith in</p> <p>8 any data in this particular paper, or page, 183, can you</p> <p>9 place faith in any particular page in this dog study?</p> <p>10 A. Can you show me which one?</p> <p>11 Q. No, that's my question. My question stands.</p> <p>12 A. You know, mechanical testing of material like</p> <p>13 polypropylene has to be done carefully. You need to</p> <p>14 test multiple samples. You need to follow a protocol.</p> <p>15 I don't really see enough of the protocol here to be</p> <p>16 able to evaluate it.</p> <p>17 These data have not stood the scrutiny of peer</p> <p>18 review, to my knowledge. If they're peer-reviewed and</p> <p>19 somebody looked at them, I would accept them, but you're</p> <p>20 asking me to accept a table of data where I don't even</p> <p>21 know how many times the test was run, and so I can't</p> <p>22 comment, I can't accept it.</p> <p>23 Q. Well, Doctor, if you can't rely on the page</p> <p>24 that gives the test data, you can't rely on the</p>	<p style="text-align: right;">Page 160</p> <p>1 and the elongation is plotted out at Time 0; is that</p> <p>2 right?</p> <p>3 A. It says it's plotting break strength --</p> <p>4 Q. Break strength and elongation at Time 0.</p> <p>5 A. -- versus elongation, but break strength has to</p> <p>6 do with the material actually breaking. So how do you</p> <p>7 measure break strength when the material continues to</p> <p>8 elongate? These sort of data are normally presented</p> <p>9 stress versus strain. That's where you get toughness.</p> <p>10 Q. I understand. And, in fact, stress and strain</p> <p>11 is another word for breaking strength and elongation,</p> <p>12 isn't it?</p> <p>13 A. No. Breaking means failure of the sample.</p> <p>14 Stress is force per unit area. Now, percent of</p> <p>15 elongation, elongation and strain, I'll agree they're</p> <p>16 very related.</p> <p>17 Q. Elongation and strain; correct?</p> <p>18 A. Yeah, they're definitely related.</p> <p>19 Q. And breaking strength and stress are related,</p> <p>20 aren't they?</p> <p>21 A. Well, a breaking strength is the ultimate</p> <p>22 tensile strength of a material.</p> <p>23 Q. Until it breaks; correct?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 159</p> <p>1 conclusions of the dog study, can you?</p> <p>2 A. There may be some things in here that I think</p> <p>3 are adequately documented.</p> <p>4 Q. My question is a yes or no, and I need a yes or</p> <p>5 no. If you can't rely on the page that gives the test</p> <p>6 data, you can't rely on the conclusions of the dog</p> <p>7 study, can you; yes or no?</p> <p>8 A. Yes.</p> <p>9 Q. Yes, I'm right?</p> <p>10 A. Yes, I agree with you.</p> <p>11 (Mays Exhibit No. 7 was marked for</p> <p>12 identification.)</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. Doctor, handing you what we'll mark as Exhibit</p> <p>15 No. 7 to your deposition. Here we have a toughness</p> <p>16 curve; right?</p> <p>17 A. Yes.</p> <p>18 Q. And we have breaking strength as the Y axis and</p> <p>19 elongation as the X axis; correct?</p> <p>20 A. Yeah, this is kind of a peculiar way to present</p> <p>21 the data.</p> <p>22 Q. And, Doctor, this shows that toughness -- well,</p> <p>23 strike that.</p> <p>24 You can see the red where the breaking strength</p>	<p style="text-align: right;">Page 161</p> <p>1 Q. And then if you --</p> <p>2 A. But how can you plot it down here where it</p> <p>3 hasn't broken?</p> <p>4 Q. Just stay with me and my questions, Doctor.</p> <p>5 Okay?</p> <p>6 A. Okay.</p> <p>7 Q. If you look at this, this plots out at Year 0</p> <p>8 the elongation and breaking strength data points from</p> <p>9 the seven-year dog study; correct? At Year 0, under</p> <p>10 red?</p> <p>11 A. It shows elongation 37 percent and that it</p> <p>12 broke at 1.68 pounds.</p> <p>13 Q. And that's the exact data that was found in the</p> <p>14 Burkley dog study; correct?</p> <p>15 A. This looks familiar, yes.</p> <p>16 Q. And, Doctor, when we look at Year 7 on</p> <p>17 Exhibit 7, that shows the elongation at 1.6 pounds and</p> <p>18 the breaking strength -- I'm sorry, strike that.</p> <p>19 At Year 7, do you see Year 7 --</p> <p>20 A. Yes.</p> <p>21 Q. -- it shows breaking strength at 1.6 pounds; is</p> <p>22 that right?</p> <p>23 A. That's what it says, yes.</p> <p>24 Q. And it shows 78 percent elongation; correct?</p>

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<p style="text-align: right;">Page 162</p> <p>1 A. That's what it shows.</p> <p>2 Q. And if we look at the area under the curve for</p> <p>3 Year 7, it's much greater than at Time 0; correct?</p> <p>4 A. The area under the curve is greater, yes.</p> <p>5 Q. And, in fact, it almost doubled, didn't it?</p> <p>6 A. That would be about right, yes.</p> <p>7 Q. And, Doctor, what does this tell you about</p> <p>8 toughness when you look at the physical and mechanical</p> <p>9 properties of the sutures?</p> <p>10 A. Again, I would have to know more about this</p> <p>11 test. Was it performed 10 times and this is an average?</p> <p>12 Was it a single run? I would have to know more. I</p> <p>13 can't just take this plot out of context and draw</p> <p>14 conclusions on it.</p> <p>15 Q. Doctor, a nick in a fishing line wouldn't</p> <p>16 increase toughness, would it?</p> <p>17 A. No.</p> <p>18 Q. Doctor, can you explain -- first of all, do you</p> <p>19 agree that the data from the seven-year dog study shows</p> <p>20 an increase in toughness of the sutures?</p> <p>21 A. I don't know enough to establish the validity</p> <p>22 of this data and exactly what was done.</p> <p>23 Q. You can't answer that question yes or no?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 164</p> <p>1 A. Yes.</p> <p>2 Q. And so is Prolene?</p> <p>3 A. Yes.</p> <p>4 Q. And if Prolene does not have an ionic charge,</p> <p>5 then that means a material will not -- or a compound</p> <p>6 will not bind to it; correct?</p> <p>7 A. That's not necessarily so.</p> <p>8 Q. Why not?</p> <p>9 A. A lot of materials bind to other materials</p> <p>10 where there's no charge present.</p> <p>11 Q. Well, Prolene is neither acidic nor basic; is</p> <p>12 that right?</p> <p>13 A. That's correct.</p> <p>14 Q. And a dye staining to Prolene requires an</p> <p>15 acidic group or a basic group to bond with it, doesn't</p> <p>16 it?</p> <p>17 A. To bond with it.</p> <p>18 Q. To bond with it; correct?</p> <p>19 A. It might bond through some other mechanism. It</p> <p>20 might bond through a carbonyl that's been introduced by</p> <p>21 oxidation. There's some level of residual double bonds</p> <p>22 in polypropylene as an impurity, and it might add across</p> <p>23 that double bond.</p> <p>24 Q. Doctor, based on the chemistry, will oxidized</p>
<p style="text-align: right;">Page 163</p> <p>1 Q. You can't answer that question one way or the</p> <p>2 other, can you?</p> <p>3 A. No.</p> <p>4 Q. Doctor, I see in your -- I see in your CV that</p> <p>5 you have an interest in charged polymers; is that</p> <p>6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. You're an expert on charged polymers?</p> <p>9 A. Well, we've done a fair bit of work with</p> <p>10 charged polymers.</p> <p>11 Q. You know enough about them to talk about them</p> <p>12 intelligently, don't you?</p> <p>13 A. I think so.</p> <p>14 Q. And you'll agree that polypropylene is</p> <p>15 nonionic?</p> <p>16 A. That's correct.</p> <p>17 Q. So is Prolene? Prolene is nonionic?</p> <p>18 A. Correct.</p> <p>19 Q. It doesn't have an ionic charge one way or the</p> <p>20 other; is that right?</p> <p>21 A. That's right.</p> <p>22 Q. And polypropylene is hydrophobic?</p> <p>23 A. Yes.</p> <p>24 Q. And polypropylene is pH neutral?</p>	<p style="text-align: right;">Page 165</p> <p>1 Prolene show any color if subjected to a staining</p> <p>2 process?</p> <p>3 A. Oxidized Prolene could very well show color.</p> <p>4 Q. How so?</p> <p>5 A. By interacting with the dye.</p> <p>6 Q. And with a chemical interaction?</p> <p>7 A. It could be physical. It could be chemical.</p> <p>8 Q. All right. Describe the chemical reaction for</p> <p>9 me, please, sir.</p> <p>10 A. There might be some functional group on the dye</p> <p>11 that might react with the carboxylic acid group.</p> <p>12 Q. Let's talk about hematoxylin. Are you familiar</p> <p>13 with hematoxylin?</p> <p>14 A. I'm really not familiar with hematoxylin.</p> <p>15 Q. Any reason to dispute it's a positive compound?</p> <p>16 A. I simply don't know one way or the other.</p> <p>17 Q. And I want you to assume for purposes of this</p> <p>18 question that hematoxylin is a positive compound. Okay?</p> <p>19 A. Positively charged?</p> <p>20 Q. Correct.</p> <p>21 A. Okay.</p> <p>22 Q. If it's positively charged, will it bind to</p> <p>23 Prolene?</p> <p>24 A. It might.</p>

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Jimmy W. Mays, Ph.D.

<p style="text-align: right;">Page 166</p> <p>1 Q. How so?</p> <p>2 A. I simply would need to know more about its</p> <p>3 structure.</p> <p>4 Q. But my question is: How so, sir?</p> <p>5 A. You know, it might just do it through</p> <p>6 hydrophobic group interactions. Hydrophobic things bind</p> <p>7 to hydrophobic things all the time.</p> <p>8 Q. Can you testify to a reasonable degree of</p> <p>9 scientific certainty whether or not hematoxylin will</p> <p>10 bind to Prolene?</p> <p>11 A. I simply don't know.</p> <p>12 Q. And, Doctor, can you testify to a reasonable</p> <p>13 degree of scientific certainty whether eosin will bind</p> <p>14 to Prolene?</p> <p>15 A. I simply don't know.</p> <p>16 Q. You will agree that there must be a chemical</p> <p>17 reaction between the dye and Prolene for there to be</p> <p>18 stain in color; correct?</p> <p>19 A. I don't think it necessarily has to be a</p> <p>20 chemical reaction. It could just be a physical</p> <p>21 phenomenon. Hydrogen bonding or something like that</p> <p>22 could do it.</p> <p>23 Q. Can you testify to that to a reasonable degree</p> <p>24 of scientific certainty?</p>	<p style="text-align: right;">Page 168</p> <p>1 Q. You'll agree that that's one of the best</p> <p>2 polymer science schools in the country, wouldn't you,</p> <p>3 sir?</p> <p>4 A. It's a good one. The one I did my PhD at is,</p> <p>5 arguably, number one.</p> <p>6 Q. Were you a student of Dr. Thames?</p> <p>7 A. I was not.</p> <p>8 Q. Do you know him?</p> <p>9 A. I did.</p> <p>10 Q. Do you have an opinion of him?</p> <p>11 A. Yes.</p> <p>12 Q. And what's your opinion of his polymer science</p> <p>13 expertise?</p> <p>14 A. I think he's a good paint chemist.</p> <p>15 Q. Anything else?</p> <p>16 A. That's all.</p> <p>17 Q. Do you intend to offer any opinions regarding</p> <p>18 this litigation that we've not already discussed or</p> <p>19 contained in your expert report?</p> <p>20 A. I may. My expert report contained the issues</p> <p>21 at the time I wrote it, but I may become aware of</p> <p>22 additional information. I may get samples to test. Who</p> <p>23 knows?</p> <p>24 Q. Doctor, going back to Exhibit 7, you can't</p>
<p style="text-align: right;">Page 167</p> <p>1 A. Yes.</p> <p>2 Q. Have you ever attempted to stain a Prolene?</p> <p>3 A. I have not.</p> <p>4 Q. Have you ever seen Prolene hold any type of</p> <p>5 color?</p> <p>6 A. I have not.</p> <p>7 Q. Doctor, before we wrap up, I want to ask you</p> <p>8 one question. Does the pelvic region have more reactive</p> <p>9 oxygen species than the abdomen?</p> <p>10 A. I don't know.</p> <p>11 Q. And have you ever seen a study comparing the</p> <p>12 two areas of the body?</p> <p>13 A. In terms of?</p> <p>14 Q. The concentration level of reactive oxygen</p> <p>15 species.</p> <p>16 A. No.</p> <p>17 Q. Your alma mater is University of Southern</p> <p>18 Mississippi?</p> <p>19 A. Yes, I did my undergraduate studies there.</p> <p>20 Q. Proud of your education?</p> <p>21 A. Yes.</p> <p>22 Q. Did you study at the Shelby Freland Thames</p> <p>23 School of Polymer Science?</p> <p>24 A. It wasn't there when I was there.</p>	<p style="text-align: right;">Page 169</p> <p>1 explain why toughness increased, can you?</p> <p>2 A. I'm not convinced that toughness did increase.</p> <p>3 Q. Can you explain, Doctor, why toughness</p> <p>4 increased in Exhibit 7; yes or no?</p> <p>5 A. No, I can't.</p> <p>6 Q. Thank you. Have you understood all my</p> <p>7 questions?</p> <p>8 A. Most of them. I tried to ask for clarification</p> <p>9 when I didn't.</p> <p>10 Q. And did I give you clarification at that time?</p> <p>11 A. In most instances, yes.</p> <p>12 Q. Is there one particular question that sticks</p> <p>13 out in your mind that I asked that you simply don't</p> <p>14 understand?</p> <p>15 A. No. You kept asking about improvement of</p> <p>16 properties as a very generic, and, you know, sometimes</p> <p>17 when one property improves, another property diminishes.</p> <p>18 So I was a little confused by that, but I think we got</p> <p>19 through it.</p> <p>20 Q. That's exactly what we saw in the Burkley dog</p> <p>21 study when we look at page 183. We saw one property</p> <p>22 decrease, such as breaking strength, and one property</p> <p>23 increase, such as elongation; correct?</p> <p>24 A. That's what that page says, but I don't -- I'm</p>

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Jimmy W. Mays, Ph.D.

<p style="text-align: right;">Page 170</p> <p>1 unable to really evaluate that data with what I have at</p> <p>2 hand.</p> <p>3 MR. HUTCHINSON: I don't have any further</p> <p>4 questions. Thank you for your time. Questions?</p> <p>5 MR. MONSOUR: We're done.</p> <p>6 MR. HUTCHINSON: Thank you.</p> <p>7 (Whereupon, the deposition concluded at</p> <p>8 12:17 p.m.)</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 172</p> <p style="text-align: center;">INSTRUCTIONS TO WITNESS</p> <p>1</p> <p>2</p> <p>3</p> <p>4 Please read your deposition over carefully and</p> <p>5 make any necessary corrections. You should state the</p> <p>6 reason in the appropriate space on the errata sheet for</p> <p>7 any corrections that are made.</p> <p>8</p> <p>9 After doing so, please sign the errata sheet</p> <p>10 and date it. It will be attached to your deposition.</p> <p>11</p> <p>12 It is imperative that you return the original</p> <p>13 errata sheet to the deposing attorney within thirty (30)</p> <p>14 days of receipt of the deposition transcript by you. If</p> <p>15 you fail to do so, the deposition transcript may be</p> <p>16 deemed to be accurate and may be used in court.</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p style="text-align: right;">Page 171</p> <p style="text-align: center;">C E R T I F I C A T E</p> <p>1</p> <p>2</p> <p>3 I, JOAN L. PITT, Registered Merit Reporter,</p> <p>4 Certified Realtime Reporter, and Florida Professional</p> <p>5 Reporter, do hereby certify that, pursuant to notice,</p> <p>6 the deposition of JIMMY W. MAYS, PhD, was duly taken on</p> <p>7 March 2, 2016, at 8:36, before me.</p> <p>8 The said JIMMY W. MAYS, PhD, was duly sworn by</p> <p>9 me according to law to tell the truth, the whole truth,</p> <p>10 and nothing but the truth, and thereupon did testify as</p> <p>11 set forth in the above transcript of testimony. The</p> <p>12 testimony was taken down stenographically by me. I do</p> <p>13 further certify that the above deposition is full,</p> <p>14 complete, and a true record of all the testimony given</p> <p>15 by the said witness.</p> <p>16</p> <p>17</p> <p>18 JOAN L. PITT, RMR, CRR, FPR</p> <p>19</p> <p>20 (The foregoing certification of this transcript</p> <p>21 does not apply to any reproduction of the same by any</p> <p>22 means, unless under the direct control and/or</p> <p>23 supervision of the certifying reporter.)</p> <p>24</p>	<p style="text-align: right;">Page 173</p> <p style="text-align: center;">----- E R R A T A -----</p> <p>1</p> <p>2</p> <p>3</p> <p>4 PAGE LINE CHANGE</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p>

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby
 acknowledge that I have read the foregoing pages,
 1 - 175, and that the same is a correct transcription of
 the answers given by me to the questions therein
 propounded, except for the corrections or changes in
 form or substance, if any, noted in the attached Errata
 Sheet.

 JIMMY W. MAYS, PhD DATE

Subscribed and sworn to before me this
 ____ day of _____, 20__.

My Commission expires: _____

 Notary Public

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LAWYER'S NOTES

PAGE	LINE
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EXHIBIT H

Duane Priddy, Ph.D.

Page 1

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC)	
REPAIR SYSTEM PRODUCTS)	Master File No.
LIABILITY LITIGATION)	2:12-MD-02327
THIS DOCUMENT RELATES TO THE)	MDL 2327
FOLLOWING CASES IN WAVE 1 OF)	JOSEPH R. GOODWIN
OF MDL 200:)	U.S. DISTRICT JUDGE
-----)	
HARRIET BEACH)	
v.)	CIVIL ACTION FILE
	No. 2:12-CV-00476
ETHICON, INC., et al.)	
-----)	
SHARON BOGGS, et al.)	
	CIVIL ACTION FILE
v.)	No. 2:12-CV-00368
ETHICON, INC., et al.)	
-----)	
JUDITH BRUHN, et al.)	
	CIVIL ACTION FILE
v.)	No. 2:12-CV-00888
ETHICON, INC., et al.)	
-----)	
JANICE COLONNA)	
	CIVIL ACTION FILE
v.)	No. 2:12-CV-01274
ETHICON, INC., et al.)	
-----)	
MARY F. CONE)	
	CIVIL ACTION FILE
v.)	No. 2:12-CV-00261
ETHICON, INC., et al.)	
-----)	
SANDRA CYRUS)	CIVIL ACTION FILE
v.)	No. 2:12-CV-01283
ETHICON, INC., et al.)	
-----)	

Videotaped Deposition of DUANE PRIDDY, PH.D.
March 8, 2016

Duane Priddy, Ph.D.

Page 2	Page 4
<p>1 AMANDA DELEON, et al.) 2 v.) CIVIL ACTION FILE) No. 2:12-CV-00358 3 ETHICON, INC., et al.) 4 ROSE GOMEZ, et al.) 5 v.) CIVIL ACTION FILE) No. 2:12-CV-00344 6 ETHICON, INC., et al.) 7 DONNA HANKINS, et al.) 8 v.) CIVIL ACTION FILE) No. 2:12-CV-01011 9 ETHICON, INC., et al.) 10 BETH HARTE, et al.) 11 v.) CIVIL ACTION FILE) No. 2:12-CV-00737 12 ETHICON, INC., et al.) 13 MARY HENDRIX, et al.) 14 v.) CIVIL ACTION FILE) No. 2:12-CV-00595 15 ETHICON, INC., et al.) 16 WILMA JOHNSON) 17 v.) CIVIL ACTION FILE) No. 2:11-CV-00809 18 ETHICON, INC., et al.) 19 JANET JONES) 20 v.) CIVIL ACTION FILE) No. 2:12-CV-00762 21 ETHICON, INC., et al.) 22) 23) 24 Videotaped Deposition of DUANE PRIDDY, PH.D.</p>	<p>1 RACHEL TAYLOR, et al.) 2 v.) CIVIL ACTION FILE) No. 2:12-CV-00765 3 ETHICON, INC., et al.) 4 PATRICIA TYLER) 5 v.) CIVIL ACTION FILE) No. 2:12-CV-00469 6 ETHICON, INC., et al.) 7 VIRGINIA WHITE, et al.) 8 v.) CIVIL ACTION FILE) No. 2:12-CV-00958 9 ETHICON, INC., et al.) 10) 11) 12) 13 Videotaped Deposition of DUANE 14 PRIDDY, PH.D., taken on behalf of the 15 Defendants, pursuant to the stipulations 16 agreed to herein, before Maxyne Bursky, 17 Registered Professional Reporter, at 111 18 Perimeter Center West, Atlanta, Georgia, 19 on the 8th day of March, 2016, commencing 20 at the hour of 9:59 a.m. 21) 22) 23) 24)</p>
Page 3	Page 5
<p>1 PAULA KRITZ, et al.) 2 v.) CIVIL ACTION FILE) No. 2:12-CV-00938 3 ETHICON, INC., et al.) 4 EDITH NOLAN) 5 v.) CIVIL ACTION FILE) No. 2:12-CV-00864 6 ETHICON, INC., et al.) 7 NOEMI PADILLA) 8 v.) CIVIL ACTION FILE) No. 2:12-CV-00567 9 ETHICON, INC., et al.) 10 MIRANDA PATTERSON) 11 v.) CIVIL ACTION FILE) No. 2:12-CV-00481 12 ETHICON, INC., et al.) 13 REBECCA PRATT) 14 v.) CIVIL ACTION FILE) No. 2:12-CV-01273 15 ETHICON, INC., et al.) 16 STACY SHULTIS) 17 v.) CIVIL ACTION FILE) No. 2:12-CV-00654 18 ETHICON, INC., et al.) 19 JANET SMITH) 20 v.) CIVIL ACTION FILE) No. 2:12-CV-00861 21 ETHICON, INC., et al.) 22) 23) 24 Videotaped Deposition of DUANE PRIDDY, PH.D.</p>	<p>1 INDEX TO EXAMINATION 2 Examination Page 3 By Mr. Hutchinson 8,168 4 By Mr. Jackson 158 5 6 INDEX TO EXHIBITS 7 Exhibit Description Page 8 1 Notice to take videotaped 8 deposition of Dr. Priddy 9 10 2 Flash drive (retained by counsel) 9 11 12 3 Expert report of Dr. Priddy 12 13 14 4 ASTM D3895-14, 8 pages 26 15 16 5 ASTM F1980-02, 6 pages 57 17 18 6 Polymer Stabilizers, A Survey with 19 Reference to Possible Applications 20 in the Conservation Field by Dr. 21 de la Rie 61 22 7 Report of Dr. Moy from Ethicon, 23 ETH.MESH.15958452-469 72 24 25 8 Antioxidant Plaox-DLTDP, 1 page 95 26 27 9 Seven Year Dog Study by Thomas 28 Barbolt, 4 pages plus 29 ETH.MESH.11336183-259, 11336071-088, 30 11336165-177, 09888187-223 and 31 11336181-183 135 32 33 10 Diagram of elongation and break 34 strength, 1 page 140 35 36) 37) 38) 39) 40)</p>

2 (Pages 2 to 5)

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Duane Priddy, Ph.D.

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<p>1 APPEARANCES OF COUNSEL: 2 On behalf of the Plaintiffs: 3 EDWARD A. WALLACE, Esq. 4 TIMOTHY E. JACKSON, Esq. 5 Wexler Wallace LLP 6 55 West Monroe Street 7 Suite 3300 8 Chicago, Illinois 60603 9 312.346.2222 10 312.346.0022 (facsimile) 11 eaw@wexlerwallace.com 12 tej@wexlerwallace.com</p> <p>13 FIDELMA L. FITZPATRICK, Esq. 14 Motley Rice LLC 15 321 South Main Street 16 Providence, Rhode Island 02903 17 401.457.7728 18 401.457.7708 (facsimile) 19 ffitzpatrick@motleyrice.com</p> <p>20 On behalf of the Defendants: 21 CHAD R. HUTCHINSON, Esq. 22 Butler Snow, LLP 23 Suite 1400 24 1020 Highland Colony Parkway Post Office Box 6010 Ridgeland, Mississippi 39158-6010 601.948.5711 601.985.4500 (facsimile) chad.hutchinson@butlersnow.com</p> <p>Also Present: PHILIP KIMBALL, Videographer - - -</p>	<p>1 MS. FITZPATRICK: Fidelma 2 Fitzpatrick on behalf of the plaintiffs. 3 THE VIDEOGRAPHER: The court 4 reporter is Maxyne Bursky and will now 5 swear in the witness. 6 DUANE PRIDDY, 7 having been first duly sworn, testifies as follows: 8 EXAMINATION 9 BY MR. HUTCHINSON: 10 Q. Good morning, Dr. Priddy. How are you? 11 A. I'm doing well. 12 Q. Good. My name is Chad Hutchinson. I'm 13 counsel for Ethicon and Johnson & Johnson. Do you 14 understand you are under oath? 15 A. I do. 16 Q. Do you understand you are giving testimony 17 subject to the penalty of perjury? 18 A. Yes. 19 Q. What is your specialty? 20 A. Polymer chemistry, materials science. 21 Q. Do you have any subspecialty? 22 A. No. 23 (Priddy Deposition Exhibit 1 was 24 marked for identification.)</p>
Page 7	Page 9
<p>1 (The signature of the witness to the 2 deposition was reserved.) 3 THE VIDEOGRAPHER: We are now on the 4 record. My name is Philip Kimball. I'm 5 a videographer for Golkow Technologies. 6 Today's date is March 8, 2016, the time 7 is 9:59 a.m. This video deposition is 8 being held in Atlanta, Georgia, in the 9 matter of Harriet Beach versus Ethicon, 10 Incorporated, et al., Case Number 11 2:12-CV-00476. 12 This case is being heard in the 13 United States District Court, Southern 14 District of West Virginia at Charleston. 15 The deponent is Duane Priddy. 16 Counsel, will you please identify 17 yourselves for the record. 18 MR. HUTCHINSON: Chad Hutchinson, 19 counsel for Ethicon and Johnson & 20 Johnson. 21 MR. JACKSON: Tim Jackson on behalf 22 of the plaintiffs. 23 MR. WALLACE: Ed Wallace on behalf 24 of the plaintiffs.</p>	<p>1 BY MR. HUTCHINSON: 2 Q. I have handed you what we will mark as 3 Exhibit 1 to your deposition. Did you bring some 4 documents responsive to that notice? 5 (Witness reviewing document.) 6 A. I read through this and I believe the 7 documents provided to you are responsive, yes. 8 (Priddy Deposition Exhibit 2 was 9 marked for identification.) 10 BY MR. HUTCHINSON: 11 Q. You have handed me a flash drive that 12 we'll mark as Exhibit 2. 13 MR. HUTCHINSON: And, Counsel, I will 14 just retain, since this is my copy, we're 15 going to mark it Exhibit 2, but I'll just 16 retain control over it; is that fair? 17 MR. JACKSON: That's fine. 18 BY MR. HUTCHINSON: 19 Q. What is included on the flash drive that 20 your counsel handed me? 21 A. A copy of my report, some documents that I 22 have reviewed, my billing record, my time log in 23 this matter. That's all I recall offhand. 24 Q. Does the flash drive contain all of the</p>

3 (Pages 6 to 9)

Duane Priddy, Ph.D.

Page 10	Page 12
<p>1 documents that you reviewed and relied upon in</p> <p>2 reaching your opinions?</p> <p>3 A. I believe so.</p> <p>4 Q. Have you reviewed this flash drive that</p> <p>5 your lawyer has handed me?</p> <p>6 A. Yes.</p> <p>7 Q. Have you been deposed as an expert in the</p> <p>8 AMS litigation?</p> <p>9 A. Yes.</p> <p>10 Q. Was that the mesh litigation?</p> <p>11 A. Yes.</p> <p>12 Q. Were you an expert, a polymer science</p> <p>13 expert in that litigation?</p> <p>14 MR. JACKSON: Objection, form.</p> <p>15 A. Yes.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. How many times have you been deposed in</p> <p>18 the AMS litigation?</p> <p>19 A. Once.</p> <p>20 Q. Have you read your testimony transcript?</p> <p>21 A. No.</p> <p>22 Q. When were you first contacted in this</p> <p>23 case?</p> <p>24 A. I'd say last September maybe.</p>	<p>1 the mesh degrades with oxidation?</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A. I believe so.</p> <p>4 (Priddy Deposition Exhibit 3 was</p> <p>5 marked for identification.)</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Doctor, I will hand you what we'll mark as</p> <p>8 Exhibit 3 to your deposition. Do you recognize that</p> <p>9 as the report that you submitted in this case?</p> <p>10 (Witness reviewing document.)</p> <p>11 A. Yes.</p> <p>12 Q. Is it complete and accurate?</p> <p>13 MR. JACKSON: Counsel, I just want</p> <p>14 to note on the record that there are two</p> <p>15 emails at the end of this document which</p> <p>16 are not part of Dr. Priddy's report.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Doctor, is that complete and accurate?</p> <p>19 A. It looks, yes, it looks like I might have</p> <p>20 to update my list of scientific articles and</p> <p>21 publications, but other than that, it's accurate.</p> <p>22 Q. Are you talking about you need to update</p> <p>23 your CV in there?</p> <p>24 A. Yes.</p>
Page 11	Page 13
<p>1 Q. Of 2015?</p> <p>2 A. Yes.</p> <p>3 Q. Who contacted you?</p> <p>4 A. Mr. Wallace.</p> <p>5 Q. What did he ask you to do?</p> <p>6 MR. JACKSON: Objection, form.</p> <p>7 A. Serve as an expert witness in the Ethicon</p> <p>8 mesh matter.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. Anything else specifically that he asked</p> <p>11 you to do?</p> <p>12 A. No.</p> <p>13 Q. Have you ever had any contacts with Mr.</p> <p>14 Wallace before?</p> <p>15 A. Yes.</p> <p>16 Q. In the AMS litigation?</p> <p>17 A. Correct.</p> <p>18 Q. Did you reach opinions similar in the AMS</p> <p>19 litigation as you have in this litigation?</p> <p>20 MR. JACKSON: Objection.</p> <p>21 A. I did not review my AMS testimony, so I</p> <p>22 don't recall.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Did you opine in the AMS litigation that</p>	<p>1 Q. Otherwise, that report is complete and</p> <p>2 accurate; is that fair?</p> <p>3 A. Yes.</p> <p>4 Q. Did anybody else work on that report other</p> <p>5 than you?</p> <p>6 A. No.</p> <p>7 Q. How much time did you spend preparing that</p> <p>8 report?</p> <p>9 A. Maybe twelve hours. I'm not sure.</p> <p>10 Q. Would the time that you spent preparing</p> <p>11 that report be reflected on the flash drive that you</p> <p>12 handed me before the deposition?</p> <p>13 A. Probably not completely because normally I</p> <p>14 under-record the time I actually spend. I actually</p> <p>15 generally spend more than what I write down.</p> <p>16 Q. Why do you under-record your time?</p> <p>17 A. Just because I -- I just like to make sure</p> <p>18 that I'm not overcharging, so I tend to be</p> <p>19 conservative when I'm recording my time.</p> <p>20 Q. Doctor, are all the opinions that you</p> <p>21 intend to offer in this case included in your expert</p> <p>22 report?</p> <p>23 A. I may end up doing a supplemental report.</p> <p>24 Q. But as we sit here right now, are all the</p>

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<p>1 opinions that you have so far included within your</p> <p>2 expert report marked as Exhibit 3?</p> <p>3 A. Yes.</p> <p>4 Q. Do you have plans sitting here now to do a</p> <p>5 supplemental report?</p> <p>6 A. Not specifically, but I may.</p> <p>7 Q. Why are you considering doing a</p> <p>8 supplemental report?</p> <p>9 A. While I was preparing for my deposition,</p> <p>10 reading through everything, I just thought it might</p> <p>11 be wise for me to do a supplemental report in the</p> <p>12 future.</p> <p>13 Q. On what specific issue would you do a</p> <p>14 supplemental report on, sir?</p> <p>15 MR. JACKSON: Objection, form.</p> <p>16 A. I'm not sure at this point. Maybe my</p> <p>17 review of the results in the 80s of Ethicon's</p> <p>18 research, some things caught my eye that I thought</p> <p>19 were important and I might generate some opinions</p> <p>20 about those in the future.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. But sitting here today, if you do a</p> <p>23 supplemental report, it is your plan to do a</p> <p>24 supplemental report only on the 1980 documents from</p>	<p>1 polypropylene?</p> <p>2 A. Not that I recall.</p> <p>3 Q. Doctor, have you ever given any</p> <p>4 presentations on mesh, Prolene, or polypropylene?</p> <p>5 A. No.</p> <p>6 Q. Have you ever worked for a medical device</p> <p>7 company before?</p> <p>8 A. Yes.</p> <p>9 Q. Did your work focus on mesh or</p> <p>10 polypropylene?</p> <p>11 A. No.</p> <p>12 Q. Other than the attorneys here, have you</p> <p>13 ever discussed your opinions with anybody else?</p> <p>14 MR. JACKSON: Objection, form.</p> <p>15 A. Are you talking about the opinions in this</p> <p>16 report?</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Yes.</p> <p>19 A. No.</p> <p>20 Q. Is it fair to say you have never discussed</p> <p>21 your opinions with any type of scientist or medical</p> <p>22 doctor or engineer; is that fair?</p> <p>23 A. That is correct.</p> <p>24 Q. Never communicated your opinions to FDA,</p>
Page 15	Page 17
<p>1 Ethicon; is that fair?</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A. At this point, that's -- yeah.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Your reliance list, Doctor, included in</p> <p>6 your expert report, is it complete and accurate?</p> <p>7 A. I believe so, yes.</p> <p>8 Q. Your CV that's included in your expert</p> <p>9 report, is that the most recent version if you added</p> <p>10 the publications that you referenced earlier?</p> <p>11 A. Yes.</p> <p>12 Q. What publications would you need to add to</p> <p>13 your CV to make it current?</p> <p>14 A. I published a paper -- well, it was just</p> <p>15 accepted by the peer reviewers -- that I am going</p> <p>16 to present at a conference here in May, and I'll</p> <p>17 add that.</p> <p>18 Q. What did you present about?</p> <p>19 A. It was understanding the science behind</p> <p>20 the failure of exercise balls.</p> <p>21 Q. Doctor, have you ever published anything</p> <p>22 regarding mesh or Prolene?</p> <p>23 A. No.</p> <p>24 Q. Have you ever published anything regarding</p>	<p>1 correct?</p> <p>2 A. That's correct.</p> <p>3 Q. Or any scientific organization?</p> <p>4 MR. JACKSON: Objection, form.</p> <p>5 A. That's correct.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Doctor, how many hours did you spend</p> <p>8 reviewing the internal Ethicon documents?</p> <p>9 A. I would say probably 14, 15 hours.</p> <p>10 Q. Did you sign a confidentiality agreement</p> <p>11 with respect to the documents you received from</p> <p>12 Ethicon?</p> <p>13 A. Well, I mean, as part of my retainer</p> <p>14 agreement there's confidentiality in there that I'm</p> <p>15 not going to share or publish or discuss.</p> <p>16 Q. I understand. Is that retainer agreement</p> <p>17 included on Exhibit 2 which is the flash drive that</p> <p>18 was handed to me before the deposition?</p> <p>19 A. I'm not sure.</p> <p>20 Q. Where is the retainer agreement?</p> <p>21 A. I would have a copy probably on my</p> <p>22 computer, or if not, a hard copy in my files.</p> <p>23 Q. When is the last time you have seen the</p> <p>24 retainer agreement?</p>

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<p>1 A. I don't recall.</p> <p>2 Q. Any reason to believe that it's been lost</p> <p>3 or destroyed?</p> <p>4 A. No.</p> <p>5 Q. Other than your retainer agreement,</p> <p>6 though, did you sign any type of paper regarding a</p> <p>7 confidentiality agreement with respect to the</p> <p>8 Ethicon documents you reviewed?</p> <p>9 A. I don't believe so.</p> <p>10 Q. Do you advertise your services?</p> <p>11 A. Yes.</p> <p>12 Q. On the internet?</p> <p>13 A. Yes.</p> <p>14 Q. Anywhere else?</p> <p>15 A. Yes.</p> <p>16 Q. Where?</p> <p>17 A. I'm listed as an expert on three or four</p> <p>18 different websites, I believe, that aren't mine.</p> <p>19 Q. Other than the internet, do you advertise</p> <p>20 your services anywhere?</p> <p>21 A. No.</p> <p>22 Q. Your billing rate is \$375 an hour for</p> <p>23 record review and 550 for testimony?</p> <p>24 A. Correct.</p>	<p>1 MR. JACKSON: Objection, calls for a</p> <p>2 legal conclusion.</p> <p>3 A. Let's put it this way: I don't advertise</p> <p>4 myself as an expert for FDA.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Is there anything on your CV that reflects</p> <p>7 your expertise as a regulatory or FDA expert?</p> <p>8 A. No.</p> <p>9 Q. Doctor, you are not a pathologist?</p> <p>10 A. I am not a pathologist.</p> <p>11 Q. Not a medical doctor?</p> <p>12 A. I am not a medical doctor.</p> <p>13 Q. Not a toxicologist?</p> <p>14 A. No.</p> <p>15 Q. Not a biostatistician?</p> <p>16 A. What?</p> <p>17 Q. A biostatistician?</p> <p>18 A. A biostatistician, I do a lot of</p> <p>19 statistical analysis, but bio, not a</p> <p>20 biostatistician.</p> <p>21 Q. Are you an epidemiologist?</p> <p>22 A. No, I'm not.</p> <p>23 Q. Are you an expert in biomaterials?</p> <p>24 MR. JACKSON: Objection, form.</p>
Page 19	Page 21
<p>1 Q. You don't consider yourself an FDA expert,</p> <p>2 do you?</p> <p>3 MR. JACKSON: Objection, form.</p> <p>4 A. I mean, I have done a lot of interaction</p> <p>5 with the FDA when I was at Dow, I did a lot of</p> <p>6 extraction studies and those kind of things to help</p> <p>7 fill out paperwork for FDA applications.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. Do you consider yourself a regulatory</p> <p>10 expert?</p> <p>11 MR. JACKSON: Objection, form.</p> <p>12 A. Again, I have done a lot of interaction</p> <p>13 with government regulatory agencies.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. I understand that, but do you hold</p> <p>16 yourself out as an expert, sir?</p> <p>17 MR. JACKSON: Objection to form.</p> <p>18 A. With regard to FDA?</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. Yes.</p> <p>21 A. I know a lot about it. That's all I can</p> <p>22 say.</p> <p>23 Q. I understand, but my question is: Do you</p> <p>24 consider yourself a regulatory or FDA expert?</p>	<p>1 A. I have done a lot of work with different</p> <p>2 biomaterials. Again, it's difficult to quantify</p> <p>3 expert or non-expert, but I have experience working</p> <p>4 with biomaterials.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. So it is difficult for you to quantify</p> <p>7 whether or not you are an expert in biomaterials?</p> <p>8 Did I understand your testimony correctly?</p> <p>9 MR. JACKSON: Objection, form.</p> <p>10 A. It's a non-quantifiable question, in my</p> <p>11 thinking.</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. Do you consider yourself an expert, sir,</p> <p>14 in biomaterials?</p> <p>15 MR. JACKSON: Objection, asked and</p> <p>16 answered.</p> <p>17 A. All I can say is I know a lot about</p> <p>18 biomaterials.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. Do you consider yourself an expert, is my</p> <p>21 question?</p> <p>22 MR. JACKSON: Objection to form.</p> <p>23 A. I'm an expert in materials.</p> <p>24 BY MR. HUTCHINSON:</p>

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<p>1 Q. What about biomaterials?</p> <p>2 A. And biomaterials are included in</p> <p>3 materials.</p> <p>4 Q. Are you an expert in biocompatibility?</p> <p>5 A. Again, I know a lot about</p> <p>6 biocompatibility. It's just difficult for me to</p> <p>7 give a yes-no answer to that when I know a lot about</p> <p>8 it, but, yeah.</p> <p>9 Q. Doctor, are you an expert in the</p> <p>10 biological response to foreign bodies?</p> <p>11 MR. JACKSON: Objection, form.</p> <p>12 A. Again, I know a lot about it but I'm</p> <p>13 not a pathologist, so.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Do you consider yourself an expert in the</p> <p>16 biological response to foreign bodies?</p> <p>17 MR. JACKSON: Objection, form.</p> <p>18 A. I'll just say I know a lot about it.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. You won't answer that question?</p> <p>21 A. I just did.</p> <p>22 MR. JACKSON: He just gave the</p> <p>23 answer.</p> <p>24 A. It's not a simple yes-no answer.</p>	<p>1 ASTM D3895 and ASTM 1980, correct?</p> <p>2 MR. JACKSON: Object to the form.</p> <p>3 A. 1980, no, I did the ASTM D3895.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Did you follow the protocols from the ASTM</p> <p>6 1980?</p> <p>7 A. I would say no. The 1980 is specific to</p> <p>8 packaging for medical devices, and so I didn't,</p> <p>9 since this was not packaging for a medical device, I</p> <p>10 did not follow that.</p> <p>11 Q. Doctor, your expert report, Page 3, states</p> <p>12 that you followed the Q10 protocol as described in</p> <p>13 ASTM F1980, correct?</p> <p>14 A. Correct.</p> <p>15 Q. What was the Q10 protocol that you</p> <p>16 followed?</p> <p>17 A. That protocol is basically a mathematical</p> <p>18 protocol where you operate under the assumption, and</p> <p>19 it is an assumption, that the oxidation rate or</p> <p>20 reaction rate doubles the kinetics of the oxidation</p> <p>21 reaction, doubles every 10 degrees Centigrade</p> <p>22 increase in temperature. So that protocol is used</p> <p>23 to extrapolate from the elevated temperature to make</p> <p>24 predictions, and I emphasize the word predictions,</p>
Page 23	Page 25
<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Do you consider yourself an expert in the</p> <p>3 design of surgical mesh?</p> <p>4 MR. JACKSON: Objection, form.</p> <p>5 A. As far as the design includes materials</p> <p>6 selection for it, yes.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. Do you consider yourself an expert in</p> <p>9 female anatomy?</p> <p>10 A. No.</p> <p>11 Q. Doctor, let's talk about the testing you</p> <p>12 did. You did some accelerated aging testing; is</p> <p>13 that correct?</p> <p>14 MR. JACKSON: Objection, form.</p> <p>15 A. The testing I did was called oxidation</p> <p>16 induction time testing. It is an accelerated test,</p> <p>17 yes.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. And at what temperature did you do it?</p> <p>20 A. 200 degrees Centigrade.</p> <p>21 Q. Why did you choose that number?</p> <p>22 A. Because it's the recommended temperature</p> <p>23 in the ASTM D3895 OIT testing standard.</p> <p>24 Q. And you followed the protocols from the</p>	<p>1 because that's all it is, of what would happen at</p> <p>2 the lower temperatures. So that's what's referred</p> <p>3 to by the Q10 protocol.</p> <p>4 Q. Is the Q10 protocol defined in the ASTM</p> <p>5 1980 protocol?</p> <p>6 MR. JACKSON: Objection, form.</p> <p>7 A. Yes.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. Is that what you followed?</p> <p>10 MR. JACKSON: Objection, form.</p> <p>11 A. I followed the Q10 protocol regarding the</p> <p>12 doubling of reaction rate every 10 degrees. That</p> <p>13 methodology for calculation is what I followed.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Did you follow anything else from ASTM</p> <p>16 1980?</p> <p>17 MR. JACKSON: Objection, form.</p> <p>18 A. No.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. Are you giving any life expectancy</p> <p>21 opinions regarding Prolene?</p> <p>22 MR. JACKSON: Objection, form.</p> <p>23 A. No, other than just general, not specific.</p> <p>24 BY MR. HUTCHINSON:</p>

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<p>1 Q. Are your general life expectancy opinions</p> <p>2 regarding Prolene included in your expert report?</p> <p>3 A. My expert opinion is that its life</p> <p>4 expectancy is not indefinite, that it degrades so</p> <p>5 it's not going to last forever.</p> <p>6 Q. But you are not giving any specific life</p> <p>7 expectancy opinions, are you, sir?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. No.</p> <p>10 (Priddy Deposition Exhibit 4 was</p> <p>11 marked for identification.)</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. I hand you what we'll mark as Exhibit 4 to</p> <p>14 your deposition.</p> <p>15 (Witness reviewing document.)</p> <p>16 Q. This is the ASTM that you followed,</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. Is this the version that you followed?</p> <p>20 A. I'm not sure if it's the dash 14 version</p> <p>21 or not. I would think it probably is not the dash</p> <p>22 14 version. It's probably an earlier version,</p> <p>23 because I have been doing OIT for many years, much</p> <p>24 earlier than 2014.</p>	<p>1 Q. Doctor, on Page 2 of your expert report,</p> <p>2 you did what is called oxidative induction time</p> <p>3 testing; is that correct?</p> <p>4 A. Correct.</p> <p>5 Q. You generated some -- I'm going to call</p> <p>6 that, by the way, OIT for short. Are you and I on</p> <p>7 the same page?</p> <p>8 A. Absolutely.</p> <p>9 Q. You generated some OIT values contained in</p> <p>10 your report; is that right?</p> <p>11 A. That is correct.</p> <p>12 Q. And you used OIT to compare the oxidative</p> <p>13 stability of 10 different Ethicon mesh samples?</p> <p>14 A. That's correct.</p> <p>15 Q. Who conducted the tests?</p> <p>16 A. A technician at Materials Engineering,</p> <p>17 Inc. located in Virgil, Illinois. They are an A2LA</p> <p>18 certified laboratory.</p> <p>19 Q. How far away is that from your office?</p> <p>20 A. About 180 miles probably.</p> <p>21 Q. Do you know the names of the person who</p> <p>22 did the testing?</p> <p>23 A. Yes.</p> <p>24 Q. What were their names?</p>
Page 27	Page 29
<p>1 Q. But 2014 -- or 14, rather, stands for</p> <p>2 the year, correct?</p> <p>3 A. Correct.</p> <p>4 Q. You used an older version of the ASTM</p> <p>5 3895?</p> <p>6 MR. JACKSON: Objection, form.</p> <p>7 A. Yes.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. Why?</p> <p>10 A. Because I have been doing it for many</p> <p>11 years preceding '14, and once I get the lab set up</p> <p>12 doing a specific test, following a specific standard</p> <p>13 in a specific way, I just don't deviate it.</p> <p>14 Q. Sir, did you ever compare the version, the</p> <p>15 older version that you used of 3895 to the most</p> <p>16 recent ASTM 3895 2014?</p> <p>17 A. No.</p> <p>18 Q. Are you aware of any changes between those</p> <p>19 two ASTM protocols?</p> <p>20 A. I would have to study it in depth to look</p> <p>21 for those differences.</p> <p>22 Q. But you can't tell us those differences</p> <p>23 now?</p> <p>24 A. No.</p>	<p>1 A. Steve Johnson is the technician that runs</p> <p>2 that test.</p> <p>3 Q. Were you present when Steve Johnson did</p> <p>4 any of the tests?</p> <p>5 A. No.</p> <p>6 Q. Did you direct the work of Steve Johnson</p> <p>7 in any way?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. To the extent of how I wanted the mesh</p> <p>10 samples analyzed, yes.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. Did you provide any written correspondence</p> <p>13 to Steve Johnson on how to do the tests?</p> <p>14 A. No.</p> <p>15 Q. Do you know how long Steve Johnson took to</p> <p>16 do the tests?</p> <p>17 MR. JACKSON: Objection, form.</p> <p>18 A. About a week.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. Eight hours a day?</p> <p>21 A. I wasn't there to watch him. I don't</p> <p>22 know.</p> <p>23 Q. Do you know how much specific time Steve</p> <p>24 Johnson did in doing the tests?</p>

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<p>1 A. No.</p> <p>2 Q. Has Steve Johnson sent you a bill for</p> <p>3 doing those tests?</p> <p>4 A. I have a credit card on file with him and</p> <p>5 when he's done, he just charges my card.</p> <p>6 Q. Has he charged your card yet?</p> <p>7 A. I have to check. I don't recall offhand.</p> <p>8 Q. Do you have any idea how much money Steve</p> <p>9 Johnson is going to charge you to do the tests that</p> <p>10 are outlined in your expert report?</p> <p>11 A. Well, I know that he charges me about \$200</p> <p>12 to run an OIT test and since he ran these ten tests,</p> <p>13 I can do the math.</p> <p>14 Q. Doctor, do you know if Steve Johnson had</p> <p>15 any help doing the tests?</p> <p>16 A. He has another technician that works with</p> <p>17 him.</p> <p>18 Q. What's that technician's name?</p> <p>19 A. It was a new hire. I don't even recall,</p> <p>20 Mark somebody.</p> <p>21 Q. Do you know how this new hire has been</p> <p>22 trained?</p> <p>23 A. I don't.</p> <p>24 Q. Have you ever met this new hire?</p>	<p>1 handled the mesh, correct?</p> <p>2 A. That is correct.</p> <p>3 Q. Have you ever asked for any chain of</p> <p>4 custody documents from Steve Johnson?</p> <p>5 A. I just talked to him to make sure that he</p> <p>6 received them. He said yes, I have. But I confirmed</p> <p>7 his receipt of the meshes that I sent to him.</p> <p>8 Q. But you have no chain of custody documents</p> <p>9 showing what Steve Johnson did with the mesh,</p> <p>10 correct?</p> <p>11 MR. JACKSON: Objection, form.</p> <p>12 A. I know he received them and analyzed them</p> <p>13 and he still has them.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. How did you ship the samples to Steve</p> <p>16 Johnson?</p> <p>17 A. UPS.</p> <p>18 Q. Where did you get the samples to ship to</p> <p>19 Steve Johnson?</p> <p>20 A. From Fidelma, an attorney.</p> <p>21 Q. When did you receive them?</p> <p>22 A. I'd have to look at the chain of custody</p> <p>23 documents. I believe it was mid-December.</p> <p>24 Q. What products did you receive?</p>
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<p>1 A. No.</p> <p>2 Q. Do you know how much time this new hire</p> <p>3 named Mark spent on this test?</p> <p>4 MR. JACKSON: Objection, form.</p> <p>5 A. I don't think he has done anything on the</p> <p>6 test. I think Steve Johnson did it all.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. And Steve Johnson did this DSC test,</p> <p>9 correct?</p> <p>10 A. That's correct.</p> <p>11 Q. Differential scanning calorimetry?</p> <p>12 A. That's correct.</p> <p>13 Q. He used some samples of Ethicon's mesh,</p> <p>14 right?</p> <p>15 A. That's correct.</p> <p>16 Q. Did you give the samples to Steve Johnson?</p> <p>17 A. I sent them to him.</p> <p>18 Q. Is that reflected in the chain of custody</p> <p>19 documents?</p> <p>20 A. It is.</p> <p>21 Q. Have you ever received any chain of</p> <p>22 custody documents from Steve Johnson?</p> <p>23 A. No.</p> <p>24 Q. Steve Johnson was the one who actually</p>	<p>1 A. I received six different TVTs and four</p> <p>2 different Gynemeshes.</p> <p>3 Q. Would you describe the Gynemeshes that you</p> <p>4 received?</p> <p>5 A. Describe them?</p> <p>6 Q. Yes, sir.</p> <p>7 MR. JACKSON: Objection, form.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. Describe them for the jury. What did they</p> <p>10 look like?</p> <p>11 A. It's just a strip of polypropylene mesh</p> <p>12 between, I assume, some stainless steel rods.</p> <p>13 Q. How else would you describe the Gynemesh</p> <p>14 that you received?</p> <p>15 MR. JACKSON: Objection, form.</p> <p>16 A. That's about all I can say about it.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. How was the Gynemesh that you received</p> <p>19 with the two stainless rods different from the six</p> <p>20 TVTs that you received?</p> <p>21 MR. JACKSON: Objection, form.</p> <p>22 A. They both had mesh between metal rods and</p> <p>23 I didn't specifically study exactly how they were</p> <p>24 different so I can't answer that question.</p>

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<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. So all products that you received had mesh</p> <p>3 between two stainless steel rods; is that correct?</p> <p>4 A. That's my recollection, yes.</p> <p>5 Q. Doctor, let's talk about the sampling that</p> <p>6 was used for the DSC. DSC is a test, by the way,</p> <p>7 right?</p> <p>8 A. Yes.</p> <p>9 Q. That's an analytical test?</p> <p>10 A. It's a piece of equipment.</p> <p>11 Q. And the purpose of the equipment is in</p> <p>12 essence to melt the product inside, fair enough?</p> <p>13 MR. JACKSON: Objection, form.</p> <p>14 A. No.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. What's the purpose of the equipment?</p> <p>17 A. It's to detect thermal heat flow, whether</p> <p>18 it be cooling or heating with plastic materials.</p> <p>19 Q. But you do that by melting the plastic</p> <p>20 material, correct?</p> <p>21 MR. JACKSON: Objection, form.</p> <p>22 A. Not necessarily.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Did you melt the samples that you received</p>	<p>1 A. Because it wasn't relevant to my opinion.</p> <p>2 Q. Doctor, was this test sample compressed or</p> <p>3 molded into a sheet format?</p> <p>4 A. No.</p> <p>5 Q. Why not?</p> <p>6 A. Because that would have given the sample</p> <p>7 another heat history, and I wanted to have the</p> <p>8 samples tested in their original use shape as</p> <p>9 monofilaments.</p> <p>10 Q. How many times was the DSC test run?</p> <p>11 MR. JACKSON: Objection, form.</p> <p>12 A. It's run once, and I had him run it in</p> <p>13 pure oxygen, switching from nitrogen to oxygen, and</p> <p>14 I also asked him to run it switching from nitrogen</p> <p>15 to air, so he ran it twice for each sample.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Do you know how long he ran it in pure</p> <p>18 nitrogen?</p> <p>19 A. You run it for so many minutes until the</p> <p>20 equipment is stable, get a smooth baseline. That's</p> <p>21 generally five minutes or so at 200.</p> <p>22 Q. But my question is, do you know how long</p> <p>23 Steve Johnson ran it in pure nitrogen?</p> <p>24 A. Whatever the standard dictates, and I</p>
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<p>1 in this case?</p> <p>2 A. At 200 degrees, that's above the melting</p> <p>3 point so they would be melted, yes.</p> <p>4 Q. How did you make the specimen sample?</p> <p>5 A. It was cut with scissors.</p> <p>6 Q. In your lab or in Steve Johnson's lab?</p> <p>7 A. Steve Johnson did the cutting.</p> <p>8 Q. Were you supervising the cutting of the</p> <p>9 samples with Steve Johnson?</p> <p>10 A. I was not present, but we discussed the</p> <p>11 protocol of how to collect the samples.</p> <p>12 Q. What was the average sheet thickness of</p> <p>13 the sample?</p> <p>14 MR. JACKSON: Objection, form.</p> <p>15 A. I don't recall.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Did you ever ask Steve Johnson about what</p> <p>18 the average sheet thickness was of the sample?</p> <p>19 A. I asked him what the thickness was.</p> <p>20 Q. What did he tell you?</p> <p>21 A. I don't recall. It was less than -- I</p> <p>22 don't recall.</p> <p>23 Q. Why is that not included in your expert</p> <p>24 report?</p>	<p>1 believe it's five minutes.</p> <p>2 Q. Do you know how long Steve Johnson ran the</p> <p>3 sample or ran the test, rather, in pure oxygen?</p> <p>4 MR. JACKSON: Objection, asked and</p> <p>5 answered.</p> <p>6 A. It's in the data. Once you switch from</p> <p>7 nitrogen to oxygen, that's time 0, and then you run</p> <p>8 it in pure oxygen until the exotherm is over and</p> <p>9 that gives you your OIT data.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Let's look at Exhibit 4 and turn with me</p> <p>12 to Page 2.</p> <p>13 A. Okay.</p> <p>14 Q. Under "9. sampling." Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. 9.1 says, "The following sample</p> <p>17 preparation procedures are recommended: the test</p> <p>18 sample is compression molded into sheet format."</p> <p>19 Did I read that correctly?</p> <p>20 A. Absolutely.</p> <p>21 Q. Why did you not follow that protocol?</p> <p>22 MR. JACKSON: Objection, form.</p> <p>23 A. Because it's recommended and, as I said</p> <p>24 previously, that would require another heat history</p>

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<p>1 on the sample, and I wanted to look at pristine mesh</p> <p>2 samples in their use state. And I didn't want to</p> <p>3 alter that.</p> <p>4 So that would have affected the results to</p> <p>5 have done it that way. And I emphasize the word</p> <p>6 "recommended," because you don't have to do it that</p> <p>7 way, it's just the recommended.</p> <p>8 Q. I understand, but fair to say that you</p> <p>9 didn't follow the recommended sampling procedure in</p> <p>10 ASTM 3895, correct?</p> <p>11 MR. JACKSON: Objection, form.</p> <p>12 A. Absolutely for good reason, it would have</p> <p>13 affected the results negatively.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Doctor, there is nothing in your expert</p> <p>16 report about how the samples were prepared, is</p> <p>17 there?</p> <p>18 A. Not in the report directly, no.</p> <p>19 Q. Why did you not include that in your</p> <p>20 expert report?</p> <p>21 A. Because it has no bearing on my opinions.</p> <p>22 Q. Doctor, did you do any type of statistical</p> <p>23 calculations to confirm that the results you got</p> <p>24 from this test that Steve Johnson did were</p>	<p>1 numbers data gave a correlation with the level of</p> <p>2 antioxidant in the mesh samples. And the reason I</p> <p>3 did that is just to confirm that there's a</p> <p>4 statistical correlation between the level of</p> <p>5 antioxidant and the OIT values because if there</p> <p>6 hadn't have been, then I would have been concerned</p> <p>7 about the validity of the results.</p> <p>8 Q. Doctor, let's look at Exhibit 4 for a</p> <p>9 minute. This is that ASTM 3895.</p> <p>10 A. Yes.</p> <p>11 Q. Bottom of Page 1, 4.3 states, "Unless</p> <p>12 otherwise specified, the analysis temperature used</p> <p>13 in this test has been arbitrarily set at 200 degrees</p> <p>14 C."</p> <p>15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. That's the temperature you used?</p> <p>18 A. Correct.</p> <p>19 Q. You used an arbitrary number?</p> <p>20 MR. JACKSON: Objection, form.</p> <p>21 A. I used the number specified in the</p> <p>22 standard, yes.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. And the number specified in the standard</p>
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<p>1 statistically significant?</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A. What I did do --</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. We are going to get to what you did do in</p> <p>6 a minute. I want to know the answer to my question</p> <p>7 first and then we'll get there.</p> <p>8 MR. JACKSON: Counsel, you have to</p> <p>9 let him answer the question.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Did you do any type of statistical</p> <p>12 calculations to --</p> <p>13 A. Yes.</p> <p>14 Q. Are those statistical calculations</p> <p>15 included in your expert report?</p> <p>16 A. No.</p> <p>17 Q. Why not?</p> <p>18 A. Just didn't include it.</p> <p>19 Q. Any reason?</p> <p>20 A. No.</p> <p>21 Q. What type of statistical calculations did</p> <p>22 you do?</p> <p>23 A. I had Steve Johnson extract the additives</p> <p>24 from the mesh samples and to determine if the OIT</p>	<p>1 is an arbitrary number, correct?</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A. It is the number that I run. Every time I</p> <p>4 do an OIT test I do it at 200 degrees. That's just</p> <p>5 always the way I run it.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. I understand that, but the number that you</p> <p>8 used is an arbitrary number according to the ASTM</p> <p>9 standard, correct?</p> <p>10 MR. JACKSON: Objection, form.</p> <p>11 A. If they -- they define it as an arbitrary</p> <p>12 number, so.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. Doctor, would you ever attempt to publish</p> <p>15 a paper in a peer-reviewed journal using arbitrary</p> <p>16 data?</p> <p>17 MR. JACKSON: Objection, form.</p> <p>18 A. I certainly would attempt to publish an</p> <p>19 article in a paper based upon following an ASTM</p> <p>20 standard.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. Would you ever attempt to publish anything</p> <p>23 in a peer-reviewed journal with an arbitrary number?</p> <p>24 MR. JACKSON: Objection, form.</p>

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<p>1 A. If it is specified in the standard, yes.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Doctor, your report states that the mesh</p> <p>4 sample was heated to 200 degrees under pure</p> <p>5 nitrogen; is that right?</p> <p>6 A. Yes.</p> <p>7 Q. That's the temperature at which you</p> <p>8 conducted this aging study?</p> <p>9 MR. JACKSON: Objection, form.</p> <p>10 A. Correct.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. That's also known as the accelerated aging</p> <p>13 temperature, correct?</p> <p>14 A. Yes.</p> <p>15 Q. That equates to roughly 392 degrees</p> <p>16 Fahrenheit?</p> <p>17 A. Correct.</p> <p>18 Q. That's about 300 degrees Fahrenheit above</p> <p>19 the normal temperature of a human being; is that</p> <p>20 correct?</p> <p>21 A. Correct.</p> <p>22 Q. And it is well above the melting point of</p> <p>23 Prolene, isn't it?</p> <p>24 MR. JACKSON: Objection, form.</p>	<p>1 testing. If there's a red flag there, it will just</p> <p>2 give you a red flag. And so with that</p> <p>3 understanding, as I say, I routinely use this test</p> <p>4 for doing lifetime predictions.</p> <p>5 Q. I understand, but with that understanding,</p> <p>6 a qualitative test does not give you lifetime</p> <p>7 predictions, does it?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. Yeah, It gives you predictions, certainly.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. It doesn't give you lifetime facts or</p> <p>12 lifetime specifics, does it?</p> <p>13 MR. JACKSON: Objection, form.</p> <p>14 A. Every time you use an accelerated test</p> <p>15 protocol to get a prediction, it's only a prediction</p> <p>16 and you have to follow it up with real life, live</p> <p>17 tests to validate.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. And you have to follow it up with real</p> <p>20 time aging tests, correct?</p> <p>21 MR. JACKSON: Objection, form.</p> <p>22 A. That is correct.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Doctor, you wouldn't rely on a qualitative</p>
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<p>1 A. Yes, it is.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. What is the melting point of Prolene?</p> <p>4 A. 165 degrees Centigrade approximately.</p> <p>5 Q. Doctor, moving to Page 2, at the top under</p> <p>6 Significance and Use, are you there with me?</p> <p>7 A. Yes.</p> <p>8 Q. It says, "The OIT is a qualitative</p> <p>9 assessment of the level (or degree) of stabilization</p> <p>10 of the material tested."</p> <p>11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. And a qualitative test is different from a</p> <p>14 quantitative test, isn't it, sir?</p> <p>15 A. That's correct.</p> <p>16 Q. A qualitative test doesn't give you a</p> <p>17 lifetime prediction, does it?</p> <p>18 MR. JACKSON: Objection, form.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. Doctor?</p> <p>21 A. It's standard practice to use data from</p> <p>22 these kind of tests to do lifetime predictions,</p> <p>23 realizing it's only a prediction. With that</p> <p>24 understanding that it has to be validated by actual</p>	<p>1 test to determine how long a polymer would retain</p> <p>2 its physical properties, would you?</p> <p>3 MR. JACKSON: Objection, form.</p> <p>4 A. I would use it for predictive purposes,</p> <p>5 yes.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Doctor, let's move on to the top of Page</p> <p>8 2. Under Note 2 it states, "The OIT measurement is</p> <p>9 an accelerated thermal-aging test and as such can be</p> <p>10 misleading."</p> <p>11 Did I read that correctly?</p> <p>12 A. Yes.</p> <p>13 Q. What does misleading mean?</p> <p>14 MR. JACKSON: Objection, form.</p> <p>15 A. What they are trying to say there is, if I</p> <p>16 have different materials, say two different</p> <p>17 polypropylenes with two different stabilizer</p> <p>18 packages, one polypropylene has additive stabilizer</p> <p>19 antioxidant A in it and another one has antioxidant</p> <p>20 stabilizer package B in it and I run an OIT and I</p> <p>21 get different values, that it would be misleading</p> <p>22 for me to say that one is better than the other.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Did you consider this statement before</p>

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<p>1 doing your testing?</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A. Yes.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Doctor, one would never expect to use</p> <p>6 Prolene in the body at 200 degrees C, would they?</p> <p>7 A. That's correct.</p> <p>8 Q. In fact, you would never expect Prolene to</p> <p>9 be exposed to a hundred percent nitrogen in vivo,</p> <p>10 would you?</p> <p>11 A. No.</p> <p>12 Q. You'd never expect Prolene to be exposed</p> <p>13 to a hundred percent oxygen in vivo, would you?</p> <p>14 MR. JACKSON: Objection, form.</p> <p>15 A. Not pure oxygen. I certainly would expect</p> <p>16 it to be exposed to oxidizing species, but not a</p> <p>17 hundred percent pure oxygen, no.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. Moving on down on Note 2, last sentence it</p> <p>20 says, "Volatile antioxidants may generate poor OIT</p> <p>21 results even though they may perform adequately at</p> <p>22 the intended use temperature of the finished</p> <p>23 product."</p> <p>24 Did I read that correctly?</p>	<p>1 level of volatility.</p> <p>2 If it comes through in less than 10</p> <p>3 minutes, it is volatile. If it takes 20 minutes to</p> <p>4 come off the GC column, you know that at</p> <p>5 200 degrees, it is not volatile. And I did the same</p> <p>6 thing for Santonox R.</p> <p>7 Q. Doctor, did you account for the volatility</p> <p>8 of any other additives contained in Prolene?</p> <p>9 A. No, I was focused on the antioxidant</p> <p>10 species.</p> <p>11 Q. Did you focus any on Procol LA-10?</p> <p>12 A. No.</p> <p>13 Q. Did you ever focus on calcium stearate?</p> <p>14 A. No. Those are lubricants, not</p> <p>15 antioxidants.</p> <p>16 Q. Doctor, the intended use temperature of</p> <p>17 the finished product, what is the intended use</p> <p>18 temperature of the finished product?</p> <p>19 MR. JACKSON: Objection, form.</p> <p>20 A. 37 degrees C or 98.6 Fahrenheit.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. It is not 200 degrees C, is it?</p> <p>23 A. No.</p> <p>24 Q. Doctor, moving on down to Note 3, "There</p>
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<p>1 A. Yes.</p> <p>2 Q. Did you consider that before you did your</p> <p>3 testing, Doctor?</p> <p>4 A. Yes.</p> <p>5 Q. Do you know whether there is a volatile</p> <p>6 antioxidant in Prolene?</p> <p>7 A. The Santonox R and the dilauryl</p> <p>8 thiodipropionate, both of those additives are not</p> <p>9 volatile. At 200 degrees they would not vaporize</p> <p>10 from the Prolene.</p> <p>11 Q. What do you base that on, Doctor?</p> <p>12 A. Just my polymer chemistry and experience</p> <p>13 working with these types of antioxidants.</p> <p>14 Q. Did you account for the volatility of</p> <p>15 DLTDP before you did your testing?</p> <p>16 A. Yes.</p> <p>17 Q. How?</p> <p>18 A. I actually asked the technician to inject</p> <p>19 a sample of pure dilauryl thiodipropionate -- this</p> <p>20 is Steve Johnson -- into the gas chromatograph to</p> <p>21 determine its relative volatility. In other words,</p> <p>22 you do that by retention time, how long does it take</p> <p>23 this chemical to -- before it makes its way through</p> <p>24 the gas chromatograph, and you get a feel for its</p>	<p>1 is no accepted sampling procedure, nor have any</p> <p>2 definitive relationships been established for</p> <p>3 comparing OIT values on field samples to those on</p> <p>4 unused products. Hence, the use of such values for</p> <p>5 determining life expectancy is uncertain and</p> <p>6 subjective."</p> <p>7 Did I read that correctly?</p> <p>8 A. Absolutely, yes.</p> <p>9 Q. Doctor, what would the field sample be in</p> <p>10 this particular case?</p> <p>11 A. The Prolene mesh.</p> <p>12 Q. It would be an explant, correct?</p> <p>13 MR. JACKSON: Objection, form.</p> <p>14 A. No, it's a virgin, unused implant.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. That's what you consider to be a field</p> <p>17 sample?</p> <p>18 A. Yes.</p> <p>19 Q. What's the difference between a virgin,</p> <p>20 unused piece of Prolene and an unused product?</p> <p>21 MR. JACKSON: Objection, form.</p> <p>22 A. There is no difference.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Doctor, the ASTM that you quote says</p>

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<p>1 there have been no definitive relationships</p> <p>2 established for comparing values on field samples to</p> <p>3 those for unused products.</p> <p>4 MR. JACKSON: Objection, misstates</p> <p>5 witness testimony.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. That's what the ASTM says, correct?</p> <p>8 A. Okay.</p> <p>9 Q. And in fact, Doctor, there's been no</p> <p>10 definitive relationships established for comparing</p> <p>11 the OIT values of explant to mesh that's never been</p> <p>12 used in surgery; is that fair?</p> <p>13 A. That is fair, yes.</p> <p>14 Q. In fact, Doctor, can you stand by your</p> <p>15 opinions to a reasonable degree of scientific</p> <p>16 certainty, given that the ASTM that you used says</p> <p>17 "determining life expectancy is uncertain and</p> <p>18 subjective"?</p> <p>19 MR. JACKSON: Objection, form.</p> <p>20 A. I'm sorry, I don't understand that</p> <p>21 question. Would you repeat it, please?</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. Can you stand by your opinions, given that</p> <p>24 the ASTM that you used says "determining life</p>	<p>1 Q. Doctor, would you ever publish anything in</p> <p>2 the "American Chemical Society" journal that was</p> <p>3 uncertain and subjective?</p> <p>4 MR. JACKSON: Objection, form.</p> <p>5 A. Yes, I would.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Doctor, moving on down to Note 7, it</p> <p>8 states, "The material composition of the specimen</p> <p>9 holder can influence the OIT test result</p> <p>10 significantly."</p> <p>11 Do you see that?</p> <p>12 A. I'm sorry, where are you at?</p> <p>13 Q. At the bottom of Page 2, note 7.</p> <p>14 A. Reagents and Materials?</p> <p>15 Q. No, bottom of Page 2. It says, "The</p> <p>16 material composition of the specimen holder."</p> <p>17 Do you see that?</p> <p>18 A. I'm sorry, I'm still not with you.</p> <p>19 Could you point to where you?</p> <p>20 Q. I'll be happy to.</p> <p>21 A. Okay, thank you. Okay.</p> <p>22 Q. Do you see that, Doctor?</p> <p>23 A. Yes.</p> <p>24 Q. What type of specimen holder was used by</p>
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<p>1 expectancy is uncertain and subjective"?</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A. What I can say is this, the life</p> <p>4 expectancy is uncertain, that's correct.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. And the life expectancy is also</p> <p>7 subjective, isn't it, sir?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. All I can say is in a nutshell, this data</p> <p>10 shows that the Prolene material will not last</p> <p>11 indefinitely in the body. It is susceptible to</p> <p>12 oxidative degradation over time.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. But the life expectancy is subjective,</p> <p>15 isn't it, sir?</p> <p>16 MR. JACKSON: Objection, form.</p> <p>17 A. It is subject to the conditions in the</p> <p>18 body, yes, certainly.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. It is also subjective according to the</p> <p>21 ASTM protocol, correct?</p> <p>22 A. It's always subjective, lifetime of any</p> <p>23 article is subject to the conditions that the part</p> <p>24 is under, exposed to.</p>	<p>1 Steve Johnson?</p> <p>2 A. It's called a DSC pan.</p> <p>3 Q. What is the DSC pan that Steve Johnson</p> <p>4 used made out of?</p> <p>5 A. He told me. It's in the report and I</p> <p>6 don't recall offhand.</p> <p>7 Q. It is in your expert report?</p> <p>8 A. No, it's in his report to me.</p> <p>9 Q. Steve Johnson prepared a report and gave</p> <p>10 it to you?</p> <p>11 MR. JACKSON: Objection, form.</p> <p>12 A. It's data. He gives me the data with a</p> <p>13 little note and it tells what the pan is, but I</p> <p>14 don't recall offhand what the pan is.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. Where is the data that Steve Johnson gave</p> <p>17 you?</p> <p>18 A. It would be on my computer.</p> <p>19 Q. It is not included on this flash drive, is</p> <p>20 it, sir?</p> <p>21 A. It probably is.</p> <p>22 Q. Can you testify under oath that this data</p> <p>23 that Steve Johnson gave you is contained on this</p> <p>24 flash drive?</p>

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<p>1 MR. JACKSON: Objection, form.</p> <p>2 A. Not without checking to confirm for sure.</p> <p>3 I believe I put it on there.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Doctor, sitting here today, can you tell</p> <p>6 us the type of specimen holder that Steve Johnson</p> <p>7 used?</p> <p>8 A. A DSC pan, and I don't recall what the</p> <p>9 metal was.</p> <p>10 Q. Do you know if Steve Johnson used more</p> <p>11 than one specimen holder?</p> <p>12 A. The little DSC pans are disposable. In</p> <p>13 other words, for the OIT test, he uses a specific</p> <p>14 type of pan that he knows to be, not influence the</p> <p>15 data and that's the type of pan he uses. I just</p> <p>16 don't recall offhand what the metal is.</p> <p>17 Q. Doctor, have you done anything to</p> <p>18 determine if the specimen holder that Steve Johnson</p> <p>19 used affected the results?</p> <p>20 MR. JACKSON: Objection, form.</p> <p>21 A. As I say, he in the past has run tests,</p> <p>22 since he runs the OIT for me all the time, to</p> <p>23 confirm the OIT test as he runs it is unaffected by</p> <p>24 the pan that he uses. It's just I don't recall what</p>	<p>1 processes checked by auditors.</p> <p>2 And so the DSC pan is always the same.</p> <p>3 It's been confirmed by him not to affect the</p> <p>4 results. That's the pan he used. I just can't</p> <p>5 recall what the metal is offhand.</p> <p>6 Q. That's right. But my question to you is:</p> <p>7 Have you personally -- I'm not talking about Steve</p> <p>8 Johnson, I'm talking about you personally -- have</p> <p>9 you personally done anything to determine if the</p> <p>10 specimen holder affected the results?</p> <p>11 MR. JACKSON: Objection, asked and</p> <p>12 answered.</p> <p>13 A. Other than how I have just answered it,</p> <p>14 no.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. Doctor, can you use your DSC data to make</p> <p>17 lifetime calculations when one is in pure oxygen and</p> <p>18 the other is implanted in vivo?</p> <p>19 MR. JACKSON: Objection, form.</p> <p>20 A. I wasn't trying to do that. That wasn't</p> <p>21 the purpose. My purpose for running the test was to</p> <p>22 look at variability of ten different mesh samples.</p> <p>23 That was my intent. And so I was looking to see if,</p> <p>24 when these different samples with the same</p>
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<p>1 metal it is.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. I understand that, Doctor, but I'm asking</p> <p>4 you, have you done anything personally to determine</p> <p>5 if the specimen holder that Steve Johnson used</p> <p>6 affected the test results?</p> <p>7 A. I don't run DSC, so technicians do that.</p> <p>8 Q. Have you done anything, sir, personally to</p> <p>9 determine if the specimen holder affected the</p> <p>10 results?</p> <p>11 MR. JACKSON: Objection, asked and</p> <p>12 answered.</p> <p>13 A. As I say, it was done in the past, on past</p> <p>14 projects.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. I am talking about this project, sir.</p> <p>17 Have you personally done anything to determine if</p> <p>18 the specimen holder affected the results, yes or no?</p> <p>19 MR. JACKSON: Objection, asked and</p> <p>20 answered.</p> <p>21 A. In the sense that I made sure that he is</p> <p>22 using his standard pan under the standard operating</p> <p>23 procedures for the laboratory as an A2LA certified</p> <p>24 laboratory. They are annually audited, all their</p>	<p>1 antioxidant formulations in them, when they are</p> <p>2 suddenly exposed to oxygen, do they have the same</p> <p>3 OIT value or is it extremely variable. And I saw up</p> <p>4 to 150 percent variability from the low to the high</p> <p>5 end.</p> <p>6 The key message is that these implants</p> <p>7 have variability in their oxidation resistance.</p> <p>8 They aren't all the same. That's it. That's the</p> <p>9 only message that I was trying to figure out there.</p> <p>10 (Priddy Deposition Exhibit 5 was</p> <p>11 marked for identification.)</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. Doctor, handing you what we'll mark as</p> <p>14 Exhibit 5 to your deposition. This is the ASTM</p> <p>15 that you quoted in your expert report, correct?</p> <p>16 MR. JACKSON: Objection, form.</p> <p>17 A. Yes.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. I believe it is your testimony, you didn't</p> <p>20 follow this ASTM 1980 protocol; is that right?</p> <p>21 A. The only portion that I followed is this</p> <p>22 Q10 estimate for trying to get a feel for predicting</p> <p>23 lifetimes.</p> <p>24 Q. Why didn't you follow anything else?</p>

15 (Pages 54 to 57)

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<p>1 MR. JACKSON: Objection, form.</p> <p>2 A. Because it's not a -- it has to do with</p> <p>3 sterile medical device packages, not what's inside.</p> <p>4 So it's really not a standard that's directly</p> <p>5 applicable to this situation.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Doctor, fair to say you never did any</p> <p>8 real-time aging studies to confirm the accelerated</p> <p>9 aging study results that you generated, correct?</p> <p>10 A. That is correct.</p> <p>11 Q. All of the studies that you did are</p> <p>12 contained in your expert report; is that correct?</p> <p>13 MR. JACKSON: Objection, form.</p> <p>14 A. I mean, I mentioned a few minutes ago, I</p> <p>15 ran the OIT test under pure oxygen and then</p> <p>16 switching from nitrogen to air, and I believe that's</p> <p>17 the only deviation that was done that wasn't</p> <p>18 included in the report.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. Doctor, turn with me to Page 2.</p> <p>21 A. Of?</p> <p>22 Q. Of Exhibit 5 which is ASTM 1980.</p> <p>23 A. Yes.</p> <p>24 Q. There on Page 2, note 6.4, this is a</p>	<p>1 MR. JACKSON: Objection, form.</p> <p>2 A. No, it's just a normal, understood</p> <p>3 scientific principle that reaction rates</p> <p>4 approximately double every 10 degrees.</p> <p>5 Q. Is that based on any scientific literature</p> <p>6 that you can tell me sitting here today?</p> <p>7 A. I could, if I was pressed to do so, I</p> <p>8 could come up with textbook references, organic</p> <p>9 chemistry 101, polymer chemistry 101 where they</p> <p>10 teach this doubling of a reaction rate every</p> <p>11 10-degree principle. As I say, it's crude and it's</p> <p>12 just for ballpark, is there a flag, kind of</p> <p>13 calculations.</p> <p>14 Q. But it is your testimony, if I understand</p> <p>15 it, under oath that ASTM 1980 does not apply to the</p> <p>16 testing you did, correct?</p> <p>17 MR. JACKSON: Objection, form.</p> <p>18 A. Yes, because it's for packaging. The only</p> <p>19 reason I reference it is because of that Q10</p> <p>20 doubling of reaction rate principle.</p> <p>21 MR. JACKSON: Chad, we have been</p> <p>22 going just about an hour. Are we at a</p> <p>23 good time for a break?</p> <p>24 MR. HUTCHINSON: One more thing and</p>
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<p>1 protocol that you followed in determining the Q10</p> <p>2 level, correct?</p> <p>3 MR. JACKSON: Objection, form.</p> <p>4 A. Q10.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Am I correct?</p> <p>7 A. Not really, because they talk about three</p> <p>8 temperatures here and I only ran one temperature,</p> <p>9 200.</p> <p>10 Q. Doctor, did you follow any type of</p> <p>11 protocol in your Q10 calculations for determining</p> <p>12 the temperature that you used?</p> <p>13 MR. JACKSON: Objection, form.</p> <p>14 A. The temperature that I used?</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. Strike that. What did you use Q10 for?</p> <p>17 A. The only portion of this that I used was</p> <p>18 just what I described earlier, the doubling,</p> <p>19 approximately doubling of reaction rate every</p> <p>20 10 degrees. That's the only -- I just referenced</p> <p>21 this to support that concept for doing that crude</p> <p>22 calculation. That's all.</p> <p>23 Q. Doctor, the double reaction rate for every</p> <p>24 10 degrees, is that based on any ASTM standard?</p>	<p>1 we'll take a quick break, okay?</p> <p>2 (Priddy Deposition Exhibit 6 was</p> <p>3 marked for identification.)</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Doctor, handing you what we'll mark as</p> <p>6 Exhibit 6 to your deposition. This is the</p> <p>7 de la Rie article that you quoted in your expert</p> <p>8 report; is that correct?</p> <p>9 (Witness reviewing document.)</p> <p>10 A. Yes.</p> <p>11 Q. Did you read this before you quoted it in</p> <p>12 your expert report?</p> <p>13 A. Yes.</p> <p>14 Q. Turn to Page 17 with me, please.</p> <p>15 A. Okay.</p> <p>16 Q. At the bottom of the column on the left,</p> <p>17 the paragraph starting out with "Materials," are</p> <p>18 you there with me?</p> <p>19 A. Yes.</p> <p>20 Q. It states, "Materials which are not</p> <p>21 exposed to light" -- and by the way, mesh when</p> <p>22 planted in vivo is not exposed to light, is it?</p> <p>23 MR. JACKSON: Objection, form.</p> <p>24 A. No. Not while it is in vivo, it is not.</p>

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<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. "Materials which are not exposed to light</p> <p>3 during their normal life could be tested in heat</p> <p>4 aging experiments."</p> <p>5 In fact, that's what you did, correct, a</p> <p>6 heat aging experiment, correct, on mesh?</p> <p>7 MR. JACKSON: Objection, form.</p> <p>8 A. Yes, I did.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. It goes on to say, "But if temperatures</p> <p>11 are used which are considerably higher than the ones</p> <p>12 the material is exposed to under normal</p> <p>13 circumstances, the danger exists of introducing new</p> <p>14 degradation reactions."</p> <p>15 Did I read that correct?</p> <p>16 A. Yes, you did.</p> <p>17 Q. Doctor, did you consider that before you</p> <p>18 did your accelerated aging tests?</p> <p>19 A. Yes.</p> <p>20 Q. Did you know what de la Rie said about</p> <p>21 using higher temperatures?</p> <p>22 A. Yes.</p> <p>23 Q. How did you account for that?</p> <p>24 A. By stating that it is only a rough</p>	<p>1 time is 10:08 a.m.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Doctor, we are back on the record. Have</p> <p>4 you understood all my questions so far?</p> <p>5 A. Yes.</p> <p>6 Q. Is there anything about the testimony</p> <p>7 that you have given that you would like to change?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. Not at this point.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Turn with me to Exhibit 2. That's your</p> <p>12 expert report.</p> <p>13 A. Okay, got it.</p> <p>14 Q. On Page 3 you state you are a plastics</p> <p>15 consultant for medical supply companies?</p> <p>16 A. Yes.</p> <p>17 Q. What type of products?</p> <p>18 A. Oh, boy.</p> <p>19 Q. Let me ask you this: Any products</p> <p>20 regarding polypropylene?</p> <p>21 A. I mean, I have done materials selection</p> <p>22 work for Baxalta.</p> <p>23 Q. Let's focus on polypropylene.</p> <p>24 A. I considered polypropylene as I was</p>
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<p>1 approximation and has to be validated with actual</p> <p>2 real-time studies because of this possibility.</p> <p>3 Q. Doctor, did you do any type of calculation</p> <p>4 regarding the Arrhenius rate reaction for</p> <p>5 polypropylene?</p> <p>6 MR. JACKSON: Objection, form.</p> <p>7 A. That has been done in the literature</p> <p>8 before.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. I am asking you: Did you do any</p> <p>11 calculation for the Arrhenius rate reaction for</p> <p>12 polypropylene?</p> <p>13 MR. JACKSON: Objection, form.</p> <p>14 A. Not on my data, no, I couldn't, because I</p> <p>15 only ran at one temperature. I did not run at</p> <p>16 three temperatures. You have to run at three</p> <p>17 temperatures to do the Arrhenius calculations.</p> <p>18 MR. HUTCHINSON: We can take a quick</p> <p>19 break.</p> <p>20 THE VIDEOGRAPHER: We are now off</p> <p>21 the video record. The time is 10:01 a.m.</p> <p>22 (Recess.)</p> <p>23 THE VIDEOGRAPHER: We are back on</p> <p>24 the video record with Tape Number 2. The</p>	<p>1 selecting material, so they just asked me to</p> <p>2 recommend a material for a certain application. And</p> <p>3 I considered polypropylene and ruled it out, just</p> <p>4 didn't have the right properties for the</p> <p>5 application.</p> <p>6 Q. Doctor, have you ever selected a polymer</p> <p>7 that has a lifetime warranty?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. I don't believe so.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Doctor, would you ever guarantee to the</p> <p>12 recipients of these medical devices that you</p> <p>13 consulted for, would you ever guarantee to them that</p> <p>14 their material would never oxidize?</p> <p>15 MR. JACKSON: Objection, form.</p> <p>16 A. No.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Doctor, on Page 3 of your expert report,</p> <p>19 you reference ISOT. That stands for incipient</p> <p>20 surface oxidation time; is that correct?</p> <p>21 A. Yes.</p> <p>22 Q. Is ISOT in any ASTM standard?</p> <p>23 A. It is nowhere. That is my own acronym.</p> <p>24 Q. Doctor, you didn't use a publication to</p>

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<p>1 come up with your own acronym, did you?</p> <p>2 A. I did not.</p> <p>3 Q. You made it up just for this experiment,</p> <p>4 didn't you?</p> <p>5 MR. JACKSON: Objection, form.</p> <p>6 A. No.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. Where did you come up with your own</p> <p>9 acronym?</p> <p>10 MR. JACKSON: Objection, form.</p> <p>11 A. As I say, I have been using OIT testing</p> <p>12 for years.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. I want to talk about ISOT.</p> <p>15 A. Yes, I know. And as part of that, I look</p> <p>16 at the shape of the OIT curve because normally it is</p> <p>17 a nice, smooth transition with two slopes and when</p> <p>18 you get the baseline meandering around and doing</p> <p>19 strange things, you know that there's something</p> <p>20 going on that's not normal. And so I always, just</p> <p>21 for my own thought processes, identify the point to</p> <p>22 where something chemically starts to happen and I</p> <p>23 call that the incipient oxidation point.</p> <p>24 Q. But that's something you made up?</p>	<p>1 A. Are you talking about in the human body?</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Yes, sir.</p> <p>4 A. Hydrogen peroxide, there's all sorts of</p> <p>5 oxidizing agents.</p> <p>6 Q. All right, hydrogen peroxide. What else?</p> <p>7 A. Again, I'm not a medical doctor or a</p> <p>8 pathologist, but I have read many reports that refer</p> <p>9 to oxidizing agents being present in the body,</p> <p>10 especially with foreign body reactions. The body</p> <p>11 will generate oxidizing species.</p> <p>12 Q. Those are called reactive oxygen species,</p> <p>13 correct?</p> <p>14 A. Right, ROS.</p> <p>15 Q. My question to you is, though, can you</p> <p>16 name the oxidizing agents that you are aware of in</p> <p>17 the human body?</p> <p>18 MR. JACKSON: Objection, asked and</p> <p>19 answered.</p> <p>20 A. I just named one, hydrogen peroxide.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. Can you name any others?</p> <p>23 MR. JACKSON: Objection, asked and</p> <p>24 answered.</p>
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<p>1 A. I did, yes.</p> <p>2 Q. Doctor, if you look at Page 5, it states,</p> <p>3 polypropylene is subject to degradation or weakening</p> <p>4 by oxidative agents.</p> <p>5 A. Where are you at now?</p> <p>6 Q. Page 5.</p> <p>7 MR. JACKSON: Chad, can you let us</p> <p>8 know which paragraph you are on?</p> <p>9 MR. HUTCHINSON: Yes, I'm sorry.</p> <p>10 Second paragraph, second sentence.</p> <p>11 THE WITNESS: Okay.</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. It states, the "chemical reactions</p> <p>14 continue to occur so long as any oxidizing agents,</p> <p>15 such as those present in the human body, are</p> <p>16 present." Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Doctor, what are the names of the</p> <p>19 oxidizing agents?</p> <p>20 MR. JACKSON: Objection, form.</p> <p>21 A. Excuse me?</p> <p>22 Q. What are the names of the oxidizing agents</p> <p>23 that you reference here?</p> <p>24 MR. JACKSON: Objection, form.</p>	<p>1 A. There's all sorts of peroxidases which are</p> <p>2 oxidative enzymes.</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. Other than hydrogen peroxide and enzymes,</p> <p>5 can you name any other type of oxidizing agents?</p> <p>6 MR. JACKSON: Objection, misstates</p> <p>7 witness testimony.</p> <p>8 A. Oxygen.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. Anything else?</p> <p>11 A. That's all I can recall at this point.</p> <p>12 Q. Doctor, do you know the amount of hydrogen</p> <p>13 peroxide that's secreted in the body?</p> <p>14 MR. JACKSON: Objection, form.</p> <p>15 A. No.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Can you quantify it?</p> <p>18 MR. JACKSON: Objection.</p> <p>19 A. I cannot.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Have you ever attempted to quantify it?</p> <p>22 A. No.</p> <p>23 Q. Have you ever used any type of</p> <p>24 concentration of hydrogen peroxide to determine how</p>

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<p>1 it affects Prolene?</p> <p>2 A. I have not done that.</p> <p>3 Q. Doctor, do you have any idea how many or</p> <p>4 what type of -- strike that.</p> <p>5 Do you have any idea of the amount of</p> <p>6 enzymes, oxidizing enzymes that are secreted from</p> <p>7 the body?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. I have never measured it, no.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. To your knowledge, has it ever been</p> <p>12 quantified?</p> <p>13 A. I do not know.</p> <p>14 Q. Doctor, sitting here today, can you</p> <p>15 quantify the amount of oxidizing agents that are</p> <p>16 produced by the human body?</p> <p>17 MR. JACKSON: Objection, asked and</p> <p>18 answered.</p> <p>19 A. Are you asking have I done it or could it</p> <p>20 be done?</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. I am asking, have you done it?</p> <p>23 A. I have not done it.</p> <p>24 Q. Do you know the amount of oxidizing agents</p>	<p>1 A. Absolutely.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Doctor, do you have any idea how the</p> <p>4 concentration level of hydrogen peroxide found</p> <p>5 naturally in the body compares to 30 percent of</p> <p>6 hydrogen peroxide?</p> <p>7 MR. JACKSON: Objection, form.</p> <p>8 A. I do not.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. You would expect 30 percent hydrogen</p> <p>11 peroxide to be much stronger than the amount of</p> <p>12 peroxide found in the body, correct?</p> <p>13 MR. JACKSON: Objection, form.</p> <p>14 A. Absolutely, yes.</p> <p>15 (Priddy Deposition Exhibit 7 was</p> <p>16 marked for identification.)</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Doctor, I will hand you what's been marked</p> <p>19 as Exhibit 7 to your deposition. Doctor, this is a</p> <p>20 memo from Ethicon dated November 5, 1984. Do you</p> <p>21 see that?</p> <p>22 (Witness reviewing document.)</p> <p>23 A. I do.</p> <p>24 Q. If you look with me, please, and by the</p>
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<p>1 produced by the human body?</p> <p>2 MR. JACKSON: Objection, asked and</p> <p>3 answered.</p> <p>4 A. No.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Doctor, do you have any opinions regarding</p> <p>7 the quantity of oxidizing agents it would take to</p> <p>8 oxidize Prolene?</p> <p>9 A. Well, Prolene is an oxidizable material,</p> <p>10 so any oxidant is capable of oxidizing Prolene.</p> <p>11 Q. My question, sir: Do you have any idea</p> <p>12 about the concentration level of oxidizing agents</p> <p>13 that it would take to oxidize Prolene?</p> <p>14 A. Any detectable, measurable amount of an</p> <p>15 oxidizing species is capable of oxidizing Prolene.</p> <p>16 Q. Can you quantify that, Doctor?</p> <p>17 MR. JACKSON: Objection, form.</p> <p>18 A. A detectable, I don't know what the</p> <p>19 detection limit of a test you want to use, but if it</p> <p>20 is detectable, it is capable of oxidizing Prolene.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. What about a micromole, can a micromole</p> <p>23 oxidize Prolene?</p> <p>24 MR. JACKSON: Objection, form.</p>	<p>1 way, this is a document that you reviewed or relied</p> <p>2 on in reaching your opinions?</p> <p>3 A. I have, yes.</p> <p>4 Q. If you look with me on Page 3 at the</p> <p>5 top --</p> <p>6 MR. JACKSON: Chad, can you give us</p> <p>7 the Bates number of the page you are on?</p> <p>8 MR. HUTCHINSON: Yes, it's 15958454.</p> <p>9 MR. JACKSON: Thank you.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Top paragraph, middle sentence, it says,</p> <p>12 "Immersion, with Peroxide Changes."</p> <p>13 Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. "To ensure strength of Prolene sutures, in</p> <p>16 30 percent hydrogen peroxide after a year's time at</p> <p>17 room temperature do not produce visible surface</p> <p>18 cracks on any of the fibers."</p> <p>19 Do you see that?</p> <p>20 A. I do.</p> <p>21 Q. Doctor, do you have any reason to disagree</p> <p>22 with this statement?</p> <p>23 A. No.</p> <p>24 Q. This shows that Prolene exposed to</p>

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<p>1 30 percent hydrogen peroxide for a year did not</p> <p>2 produce visible surface cracks; is that correct?</p> <p>3 A. That's what that's saying, yes.</p> <p>4 Q. Doctor, how did you account for that when</p> <p>5 reaching your opinions in this case?</p> <p>6 A. Irrelevant.</p> <p>7 Q. Why?</p> <p>8 A. Because they didn't do anything to</p> <p>9 determine whether the material had oxidized or not.</p> <p>10 Q. Doctor, how do you know that?</p> <p>11 A. I don't see the data where they detected</p> <p>12 whether or not oxidation had actually, degradation</p> <p>13 of the material had occurred. They just looked for</p> <p>14 surface cracks.</p> <p>15 Q. Doctor, surface cracks are a form of</p> <p>16 degradation, are they not?</p> <p>17 A. Yes.</p> <p>18 Q. In fact, visible surface cracks are a form</p> <p>19 of oxidation via degradation, correct?</p> <p>20 A. Yes.</p> <p>21 Q. Doctor, what is a Bakelite cap?</p> <p>22 A. A Bakelite what?</p> <p>23 Q. Spelled B-A-K-E-L-I-T-E, do you know what</p> <p>24 a Bakelite cap is on a glass vial?</p>	<p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. Doctor, have you tested that opinion?</p> <p>4 MR. JACKSON: Objection, form.</p> <p>5 A. That is basic polymer chemistry 101.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. My question is: Have you tested that</p> <p>8 opinion?</p> <p>9 MR. JACKSON: Objection, form.</p> <p>10 A. Yes.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. Are the test results included in your</p> <p>13 expert report?</p> <p>14 A. No.</p> <p>15 Q. Doctor, what is the rate that chemicals</p> <p>16 extract the antioxidant stabilizers?</p> <p>17 MR. JACKSON: Objection, form.</p> <p>18 A. It is dependent upon conditions.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. What about conditions in vivo, what is the</p> <p>21 rate that conditions in vivo extract Santonox R or</p> <p>22 DLTDP?</p> <p>23 A. That will be dependent upon a lot of</p> <p>24 variables.</p>
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<p>1 MR. JACKSON: Objection, form.</p> <p>2 A. Yes.</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. What are Bakelite caps generally made of?</p> <p>5 A. Bakelite, which is a phenolic resin.</p> <p>6 Q. Doctor, can you explain why the hydrogen</p> <p>7 peroxide ate away the Bakelite cap and did not</p> <p>8 affect the Prolene?</p> <p>9 A. Yes.</p> <p>10 Q. How so?</p> <p>11 A. Bakelite is a very hydrophilic,</p> <p>12 water-loving, resin because phenolics are</p> <p>13 hydroxylated materials which are hydrophylic.</p> <p>14 Polypropylene is very hydrophobic, water-hating, so</p> <p>15 polypropylene repulses and does not absorb water,</p> <p>16 whereas Bakelite does absorb water. So the water,</p> <p>17 the hydrogen peroxide would penetrate into the</p> <p>18 Bakelite and allow chemical oxidation to occur.</p> <p>19 Q. Let's look at Page 5 of your expert</p> <p>20 report, Doctor.</p> <p>21 A. Page 5, okay.</p> <p>22 Q. Bottom paragraph, about the middle of the</p> <p>23 paragraph. It states, "These chemicals act to</p> <p>24 extract the antioxidant stabilizers."</p>	<p>1 Q. Doctor, can you sit here today and</p> <p>2 quantify that rate of extraction?</p> <p>3 MR. JACKSON: Objection.</p> <p>4 A. No.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Doctor, can you explain to us in chemical</p> <p>7 terms how blood extracts antioxidant stabilizers?</p> <p>8 A. You mean scientifically how?</p> <p>9 Q. Yes, sir.</p> <p>10 A. Blood contains water plus a lot of other</p> <p>11 things, it contains triglycerides, lipids, different</p> <p>12 things. And it is the oil or the hydrophobic</p> <p>13 components in blood, the fats, the oils, the lipids,</p> <p>14 that extract the stabilizers from the plastic, and</p> <p>15 even Dr., it starts with B, the Ethicon guy that did</p> <p>16 the FTIR work, he measured the level of dilauryl</p> <p>17 thiodipropionate in the surface of sutures that had</p> <p>18 been removed and saw that there was no detectable,</p> <p>19 it was all extracted out of the surface. So even</p> <p>20 Ethicon knows that these antioxidants are</p> <p>21 extractable from the material.</p> <p>22 Q. Doctor, do you know what formalin is?</p> <p>23 A. Yes.</p> <p>24 Q. You understand that formalin contains</p>

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<p>1 formaldehyde?</p> <p>2 A. Yes.</p> <p>3 Q. Is formaldehyde a solvent?</p> <p>4 A. It is normally 37 percent concentration of</p> <p>5 water, but is it a solvent? Not really.</p> <p>6 Q. Would you consider formalin to be a</p> <p>7 solvent?</p> <p>8 A. Formalin is 37 percent formaldehyde and</p> <p>9 water. Water is a terrible solvent. It is not</p> <p>10 going to extract anything of consequence from</p> <p>11 polypropylene. Polypropylene is repulsive to water.</p> <p>12 Q. But my question, sir: Is formalin a</p> <p>13 solvent?</p> <p>14 A. It is a solvent for ionic species, but it</p> <p>15 is not a solvent for like additives.</p> <p>16 Q. Doctor, would you be able to draw out the</p> <p>17 chemical structure for the reaction between blood</p> <p>18 and Santonox R?</p> <p>19 MR. JACKSON: Objection, form.</p> <p>20 A. The Santonox R does not react with blood,</p> <p>21 it reacts with oxidizing species that would be</p> <p>22 in the blood.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Doctor, if we turn to Page 7 of your</p>	<p>1 A. That's correct.</p> <p>2 Q. And a free radical is -- strike that.</p> <p>3 There is no difference between a free</p> <p>4 radical formed in the body or a free radical formed</p> <p>5 during the heat extrusion process, correct?</p> <p>6 MR. JACKSON: Objection, form.</p> <p>7 A. In the sense they are both free radicals.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. In fact, Santonox R and DLTDP are free</p> <p>10 radical scavengers, aren't they?</p> <p>11 A. DLTDP is not a free radical scavenger,</p> <p>12 Santonox R is a free radical scavenger.</p> <p>13 Q. Why do you say DLTDP is not a free radical</p> <p>14 scavenger?</p> <p>15 A. Because it works by a different mechanism.</p> <p>16 What it does is the sulfur reacts with oxygen</p> <p>17 species.</p> <p>18 It doesn't have to be a free radical</p> <p>19 oxygen, it can just be oxygen, specifically</p> <p>20 hydroperoxides, to become a higher, either a sulfone</p> <p>21 or a sulfoxide which is a higher oxidized form. The</p> <p>22 sulfur converts the hydroperoxide group to an</p> <p>23 alcohol. But that's a different chemistry. That's</p> <p>24 not free radical-based.</p>
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<p>1 expert report, top paragraph, last sentence, you</p> <p>2 reference antioxidant Santonox R that interferes</p> <p>3 with the oxidative chain reaction.</p> <p>4 A. Yes.</p> <p>5 Q. Is that correct?</p> <p>6 A. Yes.</p> <p>7 Q. Doctor, we talked about ROS earlier, just</p> <p>8 a minute ago, correct?</p> <p>9 MR. JACKSON: Objection, form.</p> <p>10 A. Yes.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. And that stands for reactive oxygen</p> <p>13 species?</p> <p>14 A. Correct.</p> <p>15 Q. And reactive oxygen species, they possess</p> <p>16 a free radical, don't they?</p> <p>17 MR. JACKSON: Objection, form.</p> <p>18 A. They can, yes.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. And a reactive oxygen species has a</p> <p>21 non-bonded electron that wants to bond with</p> <p>22 something, doesn't it?</p> <p>23 A. The ones that are free radicals, yes.</p> <p>24 Q. And a free radical is not bonded, is it?</p>	<p>1 Q. Let's talk about the chemistry for</p> <p>2 Santonox R.</p> <p>3 MR. JACKSON: Chad, he wasn't</p> <p>4 through answering his question. You got</p> <p>5 to let him finish.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Santonox R is designed to remove free</p> <p>8 radicals when they are formed, correct?</p> <p>9 A. I wouldn't say remove, but negate the</p> <p>10 effects of free -- interferes with free radical</p> <p>11 chain reactions.</p> <p>12 Q. Doctor, let's look at Page 8 at the top.</p> <p>13 You reference the testing you did, the gas</p> <p>14 chromatography, mass spectroscopy, did I say that --</p> <p>15 A. That's correct.</p> <p>16 Q. Is that the testing that you did?</p> <p>17 A. Yes.</p> <p>18 Q. Did you personally do the GS-MC testing?</p> <p>19 A. GC-MS.</p> <p>20 Q. GC-MS testing?</p> <p>21 A. I don't run lab equipment. Trained</p> <p>22 technicians run lab equipment. I worked with a</p> <p>23 technician to tell him how I wanted the test</p> <p>24 performed, yes.</p>

21 (Pages 78 to 81)

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<p>1 Q. Who did the GC-MS testing, Doctor?</p> <p>2 A. Steve Johnson.</p> <p>3 Q. He did it too?</p> <p>4 A. Yes, he is the technician that does GC-MS</p> <p>5 and the OIT test.</p> <p>6 Q. Which did Steve Johnson do first, did he</p> <p>7 do the GC-MS or the DSC testing?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. He did the OIT first and then I wanted to</p> <p>10 see if it correlated with the additives so I asked</p> <p>11 him to do GC-MS so I could see if there was a</p> <p>12 statistical correlation.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. Let's talk about the GC-MS testing that</p> <p>15 Steve Johnson did. Did Steve Johnson's GC-MS</p> <p>16 experiment follow any standard or published</p> <p>17 procedure?</p> <p>18 A. It followed what's called SOP, standard</p> <p>19 operating procedure. Again, all certified</p> <p>20 laboratories need SOPs for everything they do.</p> <p>21 Those SOPs are audited annually, and he followed</p> <p>22 his SOP for GC-MS.</p> <p>23 Q. Which SOP did Mr. Johnson follow?</p> <p>24 A. The one for GC-MS in the lab.</p>	<p>1 A. No, I did not.</p> <p>2 Q. Doctor, did Steve Johnson perform any</p> <p>3 controls in his GC-MS experiment?</p> <p>4 A. Yes.</p> <p>5 Q. What were they?</p> <p>6 A. He always puts in an internal standard in</p> <p>7 the solvent that he extracts, the additives from the</p> <p>8 plastic, and that internal standard he looks at the</p> <p>9 size of the response and the retention time to make</p> <p>10 sure that the equipment is operating. In other</p> <p>11 words, it is a known material spiked into the</p> <p>12 solvent and if that peak is not right, he knows</p> <p>13 there's an issue.</p> <p>14 Q. Did that generate data?</p> <p>15 MR. JACKSON: Chad, you have to let</p> <p>16 the witness finish his answer.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. I'm sorry, Doctor, if I interrupted you.</p> <p>19 Did that generate data?</p> <p>20 A. What do you mean?</p> <p>21 Q. Using the control, when Mr. Johnson used</p> <p>22 the control, did it generate any data?</p> <p>23 A. Yes.</p> <p>24 Q. Where is that data?</p>
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<p>1 Q. But what number?</p> <p>2 A. I don't -- it's probably in the lab report</p> <p>3 he sent me, but I don't have the number memorized.</p> <p>4 Q. Doctor, did you ever touch the GC-MS</p> <p>5 equipment?</p> <p>6 MR. JACKSON: Objection, form.</p> <p>7 A. No.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. Did you ever touch the DSC equipment?</p> <p>10 MR. JACKSON: Objection, form.</p> <p>11 A. No.</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. Have you ever even seen the GC-MS or DSC</p> <p>14 equipment?</p> <p>15 MR. JACKSON: Objection, form.</p> <p>16 A. Yes, I have.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. At Steve Johnson's lab?</p> <p>19 A. At Steve Johnson's lab. As a matter of</p> <p>20 fact I have watched him in the past run it.</p> <p>21 Q. But you didn't watch him do this</p> <p>22 experiment --</p> <p>23 A. No.</p> <p>24 Q. -- that we are here about today?</p>	<p>1 A. It would be in his GC-MS data report.</p> <p>2 Q. Is Mr. Johnson's GC-MS data report</p> <p>3 included on the flash drive that you gave me before</p> <p>4 the deposition?</p> <p>5 A. I believe so.</p> <p>6 Q. Why wasn't that GC-MS data included in</p> <p>7 your expert report?</p> <p>8 A. I included just this comment of the</p> <p>9 correlation, but I did not include the data in the</p> <p>10 report.</p> <p>11 Q. But why not? Why didn't you include the</p> <p>12 data in your report?</p> <p>13 A. I just didn't.</p> <p>14 Q. Doctor, did Steve Johnson ever try to</p> <p>15 measure the concentration level of DLTPD?</p> <p>16 A. Yes.</p> <p>17 Q. What was the result of the concentration</p> <p>18 level of DLTPD?</p> <p>19 A. When he ran the test, he did not see the</p> <p>20 DLTPD. He couldn't detect it.</p> <p>21 Q. Doctor, have you personally ever tried to</p> <p>22 measure the concentration level of DLTPD in Prolene?</p> <p>23 A. Through Steve Johnson I have attempted to</p> <p>24 do it.</p>

22 (Pages 82 to 85)

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<p style="text-align: right;">Page 86</p> <p>1 Q. But you personally?</p> <p>2 MR. JACKSON: Objection, asked and</p> <p>3 answered.</p> <p>4 A. I have not run the equipment, no.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Doctor, are you aware of any studies that</p> <p>7 show DLTDP is lost from Prolene once it is implanted</p> <p>8 in vivo?</p> <p>9 A. Yes.</p> <p>10 Q. What's the name of the study?</p> <p>11 A. That was done by Dr. Burkley, I think his</p> <p>12 name was.</p> <p>13 Q. You are talking about an internal Ethicon</p> <p>14 scientist?</p> <p>15 A. Yes.</p> <p>16 Q. Doctor, are you aware of any published</p> <p>17 peer-reviewed literature that shows DLTDP is lost</p> <p>18 from Prolene in vivo?</p> <p>19 A. Just Dr. Burkley's work.</p> <p>20 Q. And nothing else, correct?</p> <p>21 A. That's correct.</p> <p>22 Q. Doctor, have you ever read Dr. Howard</p> <p>23 Jordi's expert reports?</p> <p>24 A. I don't recall.</p>	<p style="text-align: right;">Page 88</p> <p>1 MR. JACKSON: Objection, form.</p> <p>2 A. That's correct, yes.</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. Doctor, did you do any type of appropriate</p> <p>5 testing to determine the level of DLTDP in Prolene?</p> <p>6 MR. JACKSON: Objection, form.</p> <p>7 A. Yes, I tried to. I actually had him</p> <p>8 experiment with different conditions to try to</p> <p>9 detect the DLTDP. He did find a condition where he</p> <p>10 was able to see it. It's just not -- so it's there,</p> <p>11 it's just not reported in this data.</p> <p>12 Q. What test did he use to detect DLTDP?</p> <p>13 A. GC-MS, again. It's just he ran it under</p> <p>14 different conditions.</p> <p>15 Q. Doctor, why is that information not in</p> <p>16 your expert report?</p> <p>17 A. Because the purpose for doing it was to</p> <p>18 just make sure that it was there. I wanted to make</p> <p>19 sure it was there.</p> <p>20 Q. And you confirmed it was there?</p> <p>21 A. I confirmed it was there.</p> <p>22 Q. Or rather Mr. Johnson confirmed it was</p> <p>23 there?</p> <p>24 MR. JACKSON: Objection, form.</p>
<p style="text-align: right;">Page 87</p> <p>1 Q. Do you know Dr. Howard Jordi?</p> <p>2 A. I know there's a Jordi Lab.</p> <p>3 Q. Do you know if the Jordi Labs ever</p> <p>4 detected DLTDP in Prolene?</p> <p>5 A. I don't know.</p> <p>6 Q. If Dr. Jordi's lab did detect DLTDP in</p> <p>7 Prolene, that would be inconsistent with the results</p> <p>8 of your tests, correct?</p> <p>9 MR. JACKSON: Objection, form.</p> <p>10 A. No.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. I thought you told me your tests did not</p> <p>13 detect DLTDP.</p> <p>14 A. No, I'm saying that the way the test was</p> <p>15 run, it did not detect it. He only saw a peak for</p> <p>16 the Santonox R.</p> <p>17 Q. Doctor, is it your testimony under oath</p> <p>18 that the Prolene sample that Mr. Johnson used did</p> <p>19 not have any DLTDP in it?</p> <p>20 A. No, it likely did. It's just the way</p> <p>21 that particular test was run, it was</p> <p>22 non-detectable. But -- yeah, that's all.</p> <p>23 Q. It probably wasn't the best test to</p> <p>24 determine whether or not DLTDP was in the Prolene?</p>	<p style="text-align: right;">Page 89</p> <p>1 A. Yes.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Doctor, let's go back to the GC-MS test.</p> <p>4 Did you determine the weight loss for Santonox R</p> <p>5 before Steve Johnson did his testing?</p> <p>6 A. Weight loss?</p> <p>7 Q. The weight loss rate?</p> <p>8 A. I don't understand the question. You mean</p> <p>9 by TGA?</p> <p>10 Q. Yes, by glass transition, correct.</p> <p>11 A. No, TGA is thermogravimetric analysis.</p> <p>12 It measures weight loss of materials versus</p> <p>13 temperature.</p> <p>14 Q. TGA?</p> <p>15 A. TGA.</p> <p>16 Q. Did you do any type of TGA analysis to</p> <p>17 determine the weight loss for DLTDP?</p> <p>18 A. No.</p> <p>19 Q. Did you do any type of TGA analysis to</p> <p>20 determine the weight loss of Santonox R?</p> <p>21 A. No.</p> <p>22 Q. Why not?</p> <p>23 A. As I say, the only time I was looking for</p> <p>24 volatility, if you will, in other words, loss during</p>

23 (Pages 86 to 89)

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<p>1 the heat process, was by retention time and the gas</p> <p>2 chromatograph which gives me a feel for volatility.</p> <p>3 Q. Doctor, do you know what the recommended</p> <p>4 ranges are for DLTPD and Santonox R by weight?</p> <p>5 MR. JACKSON: Objection, form.</p> <p>6 A. I mean, that's application-specific. I</p> <p>7 know what the formulation for Prolene, has a target</p> <p>8 range of weight.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. Do you know what the target range of</p> <p>11 weight of DLTPD and Santonox R is for Prolene?</p> <p>12 A. I have seen it. It seems like it was</p> <p>13 between 2,000 and 4,000 parts per million or .2 to</p> <p>14 .4 percent, I think, in that range. It's probably</p> <p>15 not correct, but in that ballpark.</p> <p>16 Q. Doctor, do you know what the weight loss</p> <p>17 rate is for DLTPD?</p> <p>18 A. From Prolene?</p> <p>19 Q. Yes.</p> <p>20 A. Under what conditions?</p> <p>21 Q. In vivo.</p> <p>22 A. In vivo, again, the only data point I got</p> <p>23 is Dr. Burkley's data where he saw it was totally</p> <p>24 depleted from the surface after a period of time in</p>	<p>1 ramped up over time because these additives, like</p> <p>2 if the oven temperature was set at 40 degrees and</p> <p>3 you injected the sample, the additive would never</p> <p>4 come through the instruments. So you've got to keep</p> <p>5 raising the temperature until it comes through.</p> <p>6 Q. What temperature was it when the material</p> <p>7 began coming through?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. I can't tell you precisely. I can tell</p> <p>10 you it was over 200 degrees.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. Was a solvent used by Mr. Johnson with</p> <p>13 this GC-MS?</p> <p>14 A. Yes.</p> <p>15 Q. Do you know what type of solvent Mr.</p> <p>16 Johnson used?</p> <p>17 A. Methylene chloride.</p> <p>18 Q. Do you know what quantity of methylene</p> <p>19 chloride that Mr. Johnson used?</p> <p>20 A. Again, it is in his lab procedure he sent</p> <p>21 me. I don't know the number offhand.</p> <p>22 Q. Doctor, you will agree that that solvent</p> <p>23 only extracts volatile materials, correct?</p> <p>24 MR. JACKSON: Objection, form.</p>
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<p>1 vivo.</p> <p>2 Q. Doctor, do you know what the weight loss</p> <p>3 rate is for DLTPD in vivo?</p> <p>4 A. That's what I just answered. The only</p> <p>5 thing I know is from Dr. Burkley's work.</p> <p>6 Q. Same question for Santonox R: Do you know</p> <p>7 what the weight loss rate is for Santonox R in vivo?</p> <p>8 A. No.</p> <p>9 Q. Doctor, do you know what the melting point</p> <p>10 is for DLTPD?</p> <p>11 A. Not offhand.</p> <p>12 Q. Do you know what the melting point for</p> <p>13 Santonox R is?</p> <p>14 A. Again, not offhand.</p> <p>15 Q. Doctor, when we talk about the GC-MS</p> <p>16 testing, what color was the exemplar that Steve</p> <p>17 Johnson tested?</p> <p>18 A. It's in the lab report he sent me. He</p> <p>19 listed the lot number and the color.</p> <p>20 Q. What color was it?</p> <p>21 A. I don't recall if it was blue or white.</p> <p>22 I'd have to look at the lab report.</p> <p>23 Q. What temperature was the GC-MS set for?</p> <p>24 A. It's a program. Its oven temperature is</p>	<p>1 A. No.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Does it extract volatile materials?</p> <p>4 A. Yes.</p> <p>5 Q. Doctor, did you know -- my understanding</p> <p>6 in reading your report is that the GC-MS test only</p> <p>7 found Santonox R; is that right?</p> <p>8 A. That's the only stabilizer that it saw,</p> <p>9 that he identified as a stabilizer.</p> <p>10 Q. Did it pick up any other type of additives</p> <p>11 to the Prolene?</p> <p>12 MR. JACKSON: Objection, form.</p> <p>13 A. I do not believe so.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Doctor, did the GC-MS that Mr. Johnson</p> <p>16 did, did it detect Procol LA-10?</p> <p>17 A. No.</p> <p>18 Q. Why not?</p> <p>19 A. It was probably not volatile enough to</p> <p>20 make it through the instrument.</p> <p>21 Q. Do you know what the flash point is for</p> <p>22 Procol LA-10?</p> <p>23 A. Not offhand, no.</p> <p>24 Q. Do you know the melting point?</p>

24 (Pages 90 to 93)

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<p>1 A. No.</p> <p>2 Q. Do you know the flash point for Santonox</p> <p>3 R?</p> <p>4 A. No.</p> <p>5 Q. Do you know the flash point for DLTDP?</p> <p>6 A. I do not.</p> <p>7 Q. Do you know the flash point or melting</p> <p>8 point for calcium stearate?</p> <p>9 A. No.</p> <p>10 Q. Do you have any idea why Mr. Johnson's</p> <p>11 GC-MS test did not detect calcium stearate?</p> <p>12 A. Yes.</p> <p>13 Q. Why?</p> <p>14 A. It wouldn't be soluble in methylene</p> <p>15 chloride. It's only going to extract out what's</p> <p>16 soluble in that solvent.</p> <p>17 Q. Did the GCMS test detect any blue pigment?</p> <p>18 A. No.</p> <p>19 Q. Why not?</p> <p>20 A. Either it's not soluble in methylene</p> <p>21 chloride or its boiling point is too high to make</p> <p>22 it through the gas chromatograph, one of the two.</p> <p>23 Q. Do you know what the boiling point is of</p> <p>24 the CPC blue pigment?</p>	<p>1 marked for identification.)</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Doctor, I want to hand you what we'll mark</p> <p>4 as Exhibit 8 to your deposition.</p> <p>5 (Witness reviewing document.)</p> <p>6 Q. Exhibit 8 is for an antioxidant DLTDP, do</p> <p>7 you see that?</p> <p>8 A. I do.</p> <p>9 Q. The flash point for DLTDP is 150 degrees</p> <p>10 C; is that correct?</p> <p>11 A. That's what it says, yes.</p> <p>12 Q. And Doctor, do you have any reason to</p> <p>13 believe that the flash point for DLTDP would be</p> <p>14 significantly different than 150 degrees C?</p> <p>15 A. No. It sounds low but I don't have any</p> <p>16 reason to dispute it.</p> <p>17 Q. Doctor, a sample of mesh heated to</p> <p>18 200 degrees C is 50 degrees Celsius hotter than the</p> <p>19 flash point for DLTDP, isn't it?</p> <p>20 A. That's correct.</p> <p>21 Q. Doctor, that would volatilize DLTDP,</p> <p>22 wouldn't it?</p> <p>23 A. No.</p> <p>24 Q. Why not?</p>
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<p>1 A. I do not.</p> <p>2 Q. Doctor, did you ever do any type of FTIR</p> <p>3 analyses on Prolene?</p> <p>4 A. No.</p> <p>5 Q. Did Mr. Johnson to your knowledge do any</p> <p>6 type of FTIR analyses on Prolene?</p> <p>7 A. No.</p> <p>8 Q. Doctor, let's look at Page 12 of your</p> <p>9 expert report. Are you there with me?</p> <p>10 A. I am.</p> <p>11 Q. It states, "The mesh sample," in the top</p> <p>12 of the first paragraph.</p> <p>13 A. Yes.</p> <p>14 Q. "The mesh sample is heated to 200 degrees</p> <p>15 C under pure nitrogen."</p> <p>16 Is that right?</p> <p>17 A. Yes.</p> <p>18 Q. Doctor, do you know, we talked about this</p> <p>19 earlier, do you have any idea what the flash point</p> <p>20 is for DLTDP?</p> <p>21 MR. JACKSON: Objection, asked and</p> <p>22 answered.</p> <p>23 A. No.</p> <p>24 (Priddy Deposition Exhibit 8 was</p>	<p>1 A. Flash point has nothing to do with boiling</p> <p>2 point.</p> <p>3 Q. A flash point is the temperature at which</p> <p>4 an organic compound gives off enough vapor to ignite</p> <p>5 in air; is that right?</p> <p>6 A. It's ignitable in air by a spark, yes.</p> <p>7 MR. JACKSON: Chad, I am going to</p> <p>8 object to the use of this document just</p> <p>9 on foundation. I don't know what it is.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Doctor, what did you do to ensure that</p> <p>12 DLTDP or Santonox R were not burned off when Mr.</p> <p>13 Johnson heated the mesh to 200 degrees C?</p> <p>14 A. As I explained to you, I had him determine</p> <p>15 its retention time in the GC which gave me a feel</p> <p>16 for its level of volatility and based upon that</p> <p>17 data, I knew it was not a very volatile chemical.</p> <p>18 And of course when chemicals are embedded in a</p> <p>19 plastic, it's very difficult to drive them, vaporize</p> <p>20 them and get them out of the plastic at low levels.</p> <p>21 Q. Doctor, on Page 13 of your expert report</p> <p>22 under Section 11 it states, "The antioxidants,"</p> <p>23 plural, "present in the ten meshes were then</p> <p>24 extracted."</p>

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<p>1 Did I read that correctly?</p> <p>2 A. That's correct.</p> <p>3 Q. DLTDP was found as an antioxidant in this</p> <p>4 case; is that correct?</p> <p>5 MR. JACKSON: Objection, form.</p> <p>6 A. Just a minute. Let me read through this</p> <p>7 real quick.</p> <p>8 (Witness reviewing document.)</p> <p>9 A. Now, what's your question?</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. My question is, sir: Was DLTDP extracted</p> <p>12 using the methylene chloride solvent?</p> <p>13 A. All I can say is that in this particular</p> <p>14 test referred to right here, it was not detected,</p> <p>15 and I don't know exactly why it wasn't detected. I</p> <p>16 don't know if it wasn't extracted or if the</p> <p>17 conditions for the GC-MS analysis just were such</p> <p>18 that it didn't detect it.</p> <p>19 Q. Did you ever make any effort to find out</p> <p>20 why?</p> <p>21 MR. JACKSON: Objection, form.</p> <p>22 A. I asked him to try to detect DLTDP and he</p> <p>23 played around and was finally able to come up with</p> <p>24 conditions that he could see it. But it was not</p>	<p>1 A. Okay.</p> <p>2 Q. It states, "The polymer chain is</p> <p>3 disentangled."</p> <p>4 Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. Doctor, would you agree that</p> <p>7 disentanglement of polymer chains allows a polymer</p> <p>8 to elongate?</p> <p>9 MR. JACKSON: Objection, form.</p> <p>10 A. No.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. Doctor, if polymers, if polymer chains do</p> <p>13 not disentangle, would the polymer become brittle?</p> <p>14 A. If the polymer chains do not disentangle,</p> <p>15 would the polymer become brittle?</p> <p>16 Q. Correct.</p> <p>17 A. Yeah, it can, yes.</p> <p>18 Q. But you disagree that disentanglement of</p> <p>19 polymer chains allows a polymer to elongate?</p> <p>20 MR. JACKSON: Objection, misstates</p> <p>21 witness testimony.</p> <p>22 A. A polymer will elongate under stress</p> <p>23 whether or not it is entangled. So I guess I'm</p> <p>24 not --</p>
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<p>1 this particular test right here, he couldn't see it.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. What concentration level did Mr. Johnson</p> <p>4 find DLTDP in?</p> <p>5 A. The particular -- I remember numbers,</p> <p>6 hundreds of parts per million.</p> <p>7 Q. Right, but can you quantify the amount of</p> <p>8 DLTDP concentration level that Mr. Johnson found?</p> <p>9 A. I'm sorry, the question again?</p> <p>10 Q. Can you quantify the concentration level</p> <p>11 of the DLTDP that Mr. Johnson found?</p> <p>12 A. As I said, it was hundreds of parts per</p> <p>13 million. I just don't remember the exact number.</p> <p>14 Q. Did Mr. Johnson ever tell you that exact</p> <p>15 number?</p> <p>16 MR. JACKSON: Objection, form.</p> <p>17 A. Yes.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. Where would that data be included?</p> <p>20 A. In the data report.</p> <p>21 Q. Where is the data report?</p> <p>22 A. Should be on the flash drive.</p> <p>23 Q. Look at Page 9 for me, please, of your</p> <p>24 expert report under Summary, Number 2.</p>	<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Should the polymer chains become</p> <p>3 disentangled for a polymer to elongate?</p> <p>4 A. No.</p> <p>5 Q. Doctor, when you reviewed the internal</p> <p>6 documents from Ethicon, did you review any documents</p> <p>7 on biocompatibility?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 Q. Doctor?</p> <p>10 A. I'm thinking. I guess I'm not sure</p> <p>11 specifically what you are referring to, but I would</p> <p>12 say yes.</p> <p>13 Q. Do you have any opinions about the</p> <p>14 biocompatibility testing of Prolene that Ethicon</p> <p>15 did?</p> <p>16 A. I don't have an opinion on that.</p> <p>17 Q. Doctor, have you ever designed pelvic</p> <p>18 mesh?</p> <p>19 MR. JACKSON: Objection, asked and</p> <p>20 answered.</p> <p>21 A. No.</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. Have you ever done any type of</p> <p>24 biomechanical testing of pelvic mesh?</p>

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<p>1 A. The only testing I have done regarding</p> <p>2 Prolene mesh are listed in my report.</p> <p>3 Q. So we are clear, you have never done any</p> <p>4 biomechanical testing of Prolene mesh, correct?</p> <p>5 A. That's correct.</p> <p>6 Q. You have never done any type of</p> <p>7 biomechanical testing of Prolene, have you?</p> <p>8 A. No.</p> <p>9 Q. Have you ever been involved in any type of</p> <p>10 clinical research regarding Prolene?</p> <p>11 A. Other than reviewing a lot of documents on</p> <p>12 the research, no.</p> <p>13 Q. My question is, sir: Have you personally</p> <p>14 ever been involved in any type of clinical research</p> <p>15 regarding Prolene?</p> <p>16 A. Not as far as conducting the research, no.</p> <p>17 Q. Or mesh, have you ever been involved in</p> <p>18 any clinical research regarding mesh?</p> <p>19 MR. JACKSON: Objection, form.</p> <p>20 A. Just reviewing the results of the studies,</p> <p>21 that's it.</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. Have you ever tested a mesh explant?</p> <p>24 MR. JACKSON: Objection, form.</p>	<p>1 A. It's got stabilizers and additives, yes.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Prolene and polypropylene are not</p> <p>4 identical, are they?</p> <p>5 A. Prolene is polypropylene with additives.</p> <p>6 Q. And pure polypropylene is not identical to</p> <p>7 Prolene, correct?</p> <p>8 MR. JACKSON: Objection, asked and</p> <p>9 answered.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Pure polypropylene?</p> <p>12 A. Because pure, with no additives, is</p> <p>13 different than a formulation with additives, yes.</p> <p>14 Q. And Ethicon's product is a formulation</p> <p>15 with additives, correct?</p> <p>16 A. That's correct. All polypropylene</p> <p>17 products contain additives. They have to.</p> <p>18 Q. But they are different polymers?</p> <p>19 A. Polymer is the same.</p> <p>20 Q. Doctor, what medical products are you</p> <p>21 designated to give opinions about?</p> <p>22 A. You mean in legal cases? I've done</p> <p>23 consulting.</p> <p>24 Q. No, in the deposition that you are here</p>
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<p>1 A. I served as a consultant on a project</p> <p>2 several years ago involving Kugel mesh and at that</p> <p>3 point I received a mesh sample, but I don't recall</p> <p>4 actually evaluate -- or testing it.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Do you know what the chemical composition</p> <p>7 is of the Kugel mesh?</p> <p>8 A. Yes, it was a polyester.</p> <p>9 Q. It wasn't Prolene, correct?</p> <p>10 A. No.</p> <p>11 Q. Doctor, you will agree that Prolene has a</p> <p>12 chemical composition difference compared to</p> <p>13 polypropylene?</p> <p>14 A. Absolutely, yes. Compared to what?</p> <p>15 Q. Compared to polypropylene. Polypropylene</p> <p>16 and Prolene are chemically different, aren't they,</p> <p>17 sir?</p> <p>18 MR. JACKSON: Objection, form.</p> <p>19 A. Prolene meshes are polypropylene.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Doctor, as a materials scientist, would</p> <p>22 you agree that Prolene has a different chemical</p> <p>23 composition compared to pure polypropylene?</p> <p>24 MR. JACKSON: Objection, form.</p>	<p>1 for today, In Re Ethicon Pelvic Repair System</p> <p>2 Products Liability Litigation.</p> <p>3 MR. JACKSON: Objection, form.</p> <p>4 A. I was asked to opine on the use of</p> <p>5 polypropylene in the TVT and the Gynemesh product</p> <p>6 lines for urinary incontinence and the pelvic</p> <p>7 products.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. Doctor, do you know the names of the</p> <p>10 products that you are designated to give testimony</p> <p>11 about for the plaintiffs?</p> <p>12 A. As I said, the TVT products, there's like</p> <p>13 four or five of those and then the prolapse</p> <p>14 products, there are several of those.</p> <p>15 Q. Do you know the names of those products?</p> <p>16 A. Boy, I'm terrible at names. I don't</p> <p>17 remember the details of all the names, no. I was</p> <p>18 shown the names and have seen the names and, yes,</p> <p>19 but I just don't recall all the names.</p> <p>20 Q. Do the opinions that you are giving today</p> <p>21 relate to all of these products?</p> <p>22 A. If they contain polypropylene, yes.</p> <p>23 Q. Doctor, have you ever seen a TVT -- strike</p> <p>24 that.</p>

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<p>1 I am going to represent to you that you</p> <p>2 are designated in cases involving Prolene Soft mesh,</p> <p>3 Gynemesh PS, TVT, Prolift, TVT-O, Prolift+M, TVT</p> <p>4 Exact, TVT Secur, Prosima and TVT Abbrevio?</p> <p>5 A. I have seen all those names, yes.</p> <p>6 Q. Thank you. Doctor, have you ever held any</p> <p>7 of those devices in your hand?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. Yes.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. When?</p> <p>12 A. Back in December when I received the</p> <p>13 samples for lab testing.</p> <p>14 Q. Did you receive one sample of each</p> <p>15 product?</p> <p>16 A. No, I received, I think, four of the</p> <p>17 Gynemesh products and six of the TVT products.</p> <p>18 Q. So fair to say you have never held Prosima</p> <p>19 or Prolift or Prolift+M in your hands?</p> <p>20 MR. JACKSON: Objection, form.</p> <p>21 A. That's correct.</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. Doctor, do you know what the indications</p> <p>24 are for those products?</p>	<p>1 those particular products?</p> <p>2 A. Again, I've seen that information. I just</p> <p>3 don't recall it.</p> <p>4 Q. Do you know how many newtons of force are</p> <p>5 placed on the mesh in vivo?</p> <p>6 A. I do not.</p> <p>7 Q. Doctor, what do you know about the</p> <p>8 manufacturing process Ethicon uses to make Prolene?</p> <p>9 MR. JACKSON: Objection, form.</p> <p>10 A. I know that the resin is manufactured in</p> <p>11 West Virginia and then it's converted to fiber in</p> <p>12 Georgia, and then woven into mesh and sent over to</p> <p>13 Europe where it's cut and then it's shipped back to</p> <p>14 the US for sale.</p> <p>15 Q. Doctor, is the mesh woven or knitted?</p> <p>16 A. Oh, boy, I'm not sure of the semantics of</p> <p>17 the difference between those to be able to answer.</p> <p>18 Q. Doctor, do you know if Prolift+M, the mesh</p> <p>19 in Prolift+M is made of a hundred percent Prolene?</p> <p>20 A. I remember, when I looked through the data</p> <p>21 in the data sheets, I remember that some of the</p> <p>22 products have polypropylene plus another</p> <p>23 biodegradable kind of material, either</p> <p>24 polycaprolactone or glycolate biodegradable</p>
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<p>1 A. Indications?</p> <p>2 Q. Yes.</p> <p>3 A. What do you mean by indications?</p> <p>4 Q. What the product is indicated for from a</p> <p>5 medical standpoint.</p> <p>6 A. In general, yes.</p> <p>7 Q. Doctor, do you know how long those</p> <p>8 products have been on the market?</p> <p>9 A. The years vary but it started back in the</p> <p>10 1990s and then there's recent introductions as</p> <p>11 recent as, I think 2010 or '11.</p> <p>12 Q. Can you tell us the date that each of</p> <p>13 those products were introduced to the market?</p> <p>14 MR. JACKSON: Objection, form.</p> <p>15 A. Again, I have seen the dates, I just don't</p> <p>16 recall.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Do you know the physical dimensions of the</p> <p>19 mesh of each of those products?</p> <p>20 MR. JACKSON: Objection, form.</p> <p>21 A. Again, I have seen pictures and photo-</p> <p>22 graphs of them, but I don't recall exact dimensions.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Do you know the weight of the mesh of</p>	<p>1 material. So it is a hybrid system.</p> <p>2 Q. Doctor, my question is: Do you know what</p> <p>3 type of biodegradable material Prolift+M has in its</p> <p>4 mesh?</p> <p>5 MR. JACKSON: Objection, form.</p> <p>6 A. I have seen it, I just don't recall.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. Doctor, did you make any efforts to find</p> <p>9 out what type of biodegradable material is in</p> <p>10 Prolift+M?</p> <p>11 A. Other than reading the sheets that</p> <p>12 describe them, no.</p> <p>13 Q. Do you consider yourself an expert in the</p> <p>14 manufacturing process of pelvic mesh?</p> <p>15 MR. JACKSON: Objection, form.</p> <p>16 A. Just the manufacture as far as it goes to</p> <p>17 making the fibers. Once the fibers are made, I'm</p> <p>18 not an expert from that point on.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. Doctor, have you ever invented any type of</p> <p>21 polypropylene product that's turned into a fiber?</p> <p>22 A. Invented a polypropylene product, I have</p> <p>23 worked on polypropylene additive formulations. I</p> <p>24 led a group at Dow for several years in the 1990s</p>

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<p>1 where we experimented with different Dow products</p> <p>2 including polypropylene and the additives and</p> <p>3 stabilizers that need to be added to those to make</p> <p>4 various types of products including fibers.</p> <p>5 Q. Doctor, have you personally ever performed</p> <p>6 any testing to determine if Prolene degrades in</p> <p>7 vivo?</p> <p>8 A. I have not done any in vivo testing</p> <p>9 myself, no.</p> <p>10 Q. And you haven't done any loss of</p> <p>11 mechanical property testing in vivo, have you?</p> <p>12 A. I just reviewed the Ethicon documents</p> <p>13 which showed the loss of strength properties from in</p> <p>14 vivo implanted Prolene sutures.</p> <p>15 Q. But you have never done any testing, have</p> <p>16 you?</p> <p>17 MR. JACKSON: Objection, form.</p> <p>18 A. Just reviewed work of others, yes.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. In fact, you have never tested the</p> <p>21 durability of Prolene?</p> <p>22 A. In vivo?</p> <p>23 Q. Yes.</p> <p>24 A. Not directly, no.</p>	<p>1 testing of Prolene, have you?</p> <p>2 A. I sure reviewed the Ethicon documents on</p> <p>3 the Young's modulus of Prolene. I was shocked by</p> <p>4 what I saw.</p> <p>5 Q. You have never done any testing of that,</p> <p>6 have you?</p> <p>7 A. I have done modulus testing.</p> <p>8 Q. On Prolene?</p> <p>9 A. Not on Prolene, no.</p> <p>10 Q. You have had the resources available to do</p> <p>11 all of this testing of Prolene, haven't you?</p> <p>12 A. I've had it, but I had all those documents</p> <p>13 which gave me the data that I needed to opine on</p> <p>14 that issue.</p> <p>15 Q. You will agree with me that degradation</p> <p>16 affects the physical properties of the polymer?</p> <p>17 A. Absolutely, yes.</p> <p>18 Q. And it will affect the physical properties</p> <p>19 of the mesh and/or suture, correct?</p> <p>20 A. That's correct.</p> <p>21 Q. You will agree that evaluation of the</p> <p>22 physical properties of mesh is an important part in</p> <p>23 your analysis on degradation, correct?</p> <p>24 A. Absolutely, yes.</p>
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<p>1 Q. Have you ever tested the durability of</p> <p>2 Prolene in any form or fashion?</p> <p>3 MR. JACKSON: Objection, form.</p> <p>4 A. Well, yes, the OIT testing.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. What about tensile strength, have you ever</p> <p>7 tested tensile strength of Prolene, whether it be in</p> <p>8 vivo or outside the body?</p> <p>9 A. I just reviewed the Ethicon documents</p> <p>10 which do that kind of testing.</p> <p>11 Q. You have never done tensile strength</p> <p>12 testing, have you?</p> <p>13 A. I have done tensile strength testing.</p> <p>14 Q. Of Prolene?</p> <p>15 A. Not of Prolene, no.</p> <p>16 Q. You have never done elongation testing of</p> <p>17 Prolene, have you?</p> <p>18 A. Just reviewed those documents.</p> <p>19 Q. You have never done any toughness testing</p> <p>20 of Prolene, have you?</p> <p>21 MR. JACKSON: Objection, form.</p> <p>22 A. No, just reviewed the documents.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. You have never done any Young's modulus</p>	<p>1 Q. As well as oxidation?</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A. Yes.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Doctor, have you ever done any type of</p> <p>6 testing or analysis on an explanted Prolene mesh?</p> <p>7 A. Just reviewed the literature and the</p> <p>8 documents.</p> <p>9 Q. But you have never done any actual testing</p> <p>10 of an actual explanted Prolene mesh, have you?</p> <p>11 A. Not myself, no.</p> <p>12 Q. Have you ever seen a Prolene explanted</p> <p>13 mesh?</p> <p>14 A. Yes.</p> <p>15 Q. Where?</p> <p>16 A. In the literature.</p> <p>17 Q. Have you ever seen an actual Prolene</p> <p>18 explanted mesh?</p> <p>19 A. No.</p> <p>20 Q. Have you ever seen an actual Prolene</p> <p>21 explant that has become degraded?</p> <p>22 A. Yes.</p> <p>23 Q. Where?</p> <p>24 A. In the literature.</p>

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<p>1 Q. Outside the literature, have you ever seen</p> <p>2 personally a Prolene explant that has become</p> <p>3 brittle?</p> <p>4 A. No.</p> <p>5 Q. Or degraded?</p> <p>6 A. No.</p> <p>7 Q. Or oxidized?</p> <p>8 A. No.</p> <p>9 Q. Or lost physical properties?</p> <p>10 MR. JACKSON: Objection, form.</p> <p>11 A. Just in pictures in the literature.</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. In fact, you have never done any testing</p> <p>14 or analysis on the degradation of Prolene before</p> <p>15 your involvement in this case; is that correct?</p> <p>16 MR. JACKSON: Objection, asked and</p> <p>17 answered.</p> <p>18 A. Before involvement in the case, no.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. Am I correct?</p> <p>21 A. That's correct.</p> <p>22 Q. Thank you. Doctor, you were designated</p> <p>23 in -- let's look at Exhibit 1 for me, please, it is</p> <p>24 the notice of deposition.</p>	<p>1 piece of explanted mesh because of various obvious</p> <p>2 reasons.</p> <p>3 Q. Biohazardous --</p> <p>4 A. Biohazardous, yes, until I was assured</p> <p>5 that there was no issue.</p> <p>6 Q. Doctor, fair to say you have never</p> <p>7 inspected the explanted mesh from any of these 23</p> <p>8 women, correct?</p> <p>9 A. That is correct.</p> <p>10 MR. JACKSON: We have been going</p> <p>11 about another hour. Can we take a break</p> <p>12 soon?</p> <p>13 MR. HUTCHINSON: Yes.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Do you know the date that these women had</p> <p>16 implanted or explanted mesh in them?</p> <p>17 A. No.</p> <p>18 Q. Do you have any idea how long these women</p> <p>19 had their mesh in their bodies before it was</p> <p>20 explanted?</p> <p>21 A. No.</p> <p>22 Q. Do you know why from a medical or clinical</p> <p>23 standpoint, why any of these 23 plaintiffs had their</p> <p>24 mesh removed?</p>
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<p>1 A. Yes.</p> <p>2 Q. You were designated as an expert in 23</p> <p>3 case-specific cases starting with Harriet Beach,</p> <p>4 Sharon Boggs and going on down all the way to</p> <p>5 Virginia White. Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. Do you know what type of product these 23</p> <p>8 women received?</p> <p>9 MR. JACKSON: Objection, form.</p> <p>10 A. No.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. Have you ever reviewed the medical records</p> <p>13 for these 23 plaintiffs?</p> <p>14 A. No, I have not.</p> <p>15 Q. By the way, Doctor, have you ever</p> <p>16 attempted to clean an explanted piece of mesh?</p> <p>17 A. No.</p> <p>18 Q. Why do you laugh?</p> <p>19 A. Because I was sent a sample of explanted</p> <p>20 mesh and asked to analyze it and it made me very</p> <p>21 nervous.</p> <p>22 Q. Who sent it to you?</p> <p>23 A. This was the Kugel mesh case and I got to</p> <p>24 the point of where I just didn't want to handle a</p>	<p>1 MR. JACKSON: Objection, form.</p> <p>2 A. I can only make assumptions.</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. You don't have any hard facts on why the</p> <p>5 mesh --</p> <p>6 A. No.</p> <p>7 Q. Excuse me, no hard facts regarding why the</p> <p>8 mesh was removed, correct?</p> <p>9 A. Correct.</p> <p>10 Q. Doctor, can you make any prediction about</p> <p>11 when the mesh from any of these 23 different</p> <p>12 plaintiffs would have oxidized in vivo?</p> <p>13 MR. JACKSON: Objection, form.</p> <p>14 A. Based upon the results of Ethicon's</p> <p>15 testing, yes.</p> <p>16 MR. JACKSON: Chad, let's take a</p> <p>17 break now.</p> <p>18 MR. HUTCHINSON: Actually, just two</p> <p>19 more questions and we'll take a break.</p> <p>20 MR. JACKSON: I will give you two</p> <p>21 questions.</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. Doctor, can you tell us a specific date</p> <p>24 when Harriet Beach's mesh oxidized?</p>

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<p>1 MR. JACKSON: Objection, form.</p> <p>2 A. No.</p> <p>3 MR. HUTCHINSON: Thank you. We'll</p> <p>4 take a quick break.</p> <p>5 THE VIDEOGRAPHER: We are off the</p> <p>6 video record. The time is 11:08 a.m.</p> <p>7 (Recess.)</p> <p>8 THE VIDEOGRAPHER: We are back on</p> <p>9 the video record with Tape Number 3. The</p> <p>10 time is 11:18 a.m.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. Doctor, back on the record. Anything</p> <p>13 about the testimony you have given you would like to</p> <p>14 change?</p> <p>15 A. No.</p> <p>16 Q. Going back to Exhibit 1 and the list of</p> <p>17 the 23 different plaintiffs, can you tell us the</p> <p>18 date on which any of these 23 different plaintiffs</p> <p>19 had their mesh oxidized?</p> <p>20 MR. JACKSON: Objection, form.</p> <p>21 A. I could probably tell you if I had the</p> <p>22 literature when the meshes were removed.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Right, but I am asking when they were</p>	<p>1 A. That's correct.</p> <p>2 Q. Doctor, can you state to a reasonable</p> <p>3 degree of scientific certainty whether or not any of</p> <p>4 these 23 plaintiffs have had their mesh removed</p> <p>5 specifically because of degradation?</p> <p>6 A. All I can say is that the meshes removed</p> <p>7 from these women had undergone oxidation. I can say</p> <p>8 that unequivocally.</p> <p>9 Q. Doctor, did the mesh from any of these</p> <p>10 women fail?</p> <p>11 MR. JACKSON: Objection, form.</p> <p>12 A. Depends on how you define failure.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. Did the mesh from any of these women stop</p> <p>15 providing tissue support?</p> <p>16 A. I do not know that.</p> <p>17 Q. Did the mesh from any of these women lose</p> <p>18 molecular weight?</p> <p>19 A. Yes.</p> <p>20 Q. Have you ever done any molecular weight</p> <p>21 analyses on the explants from these women?</p> <p>22 A. No.</p> <p>23 Q. How can you tell us that these meshes lost</p> <p>24 molecular weight without having examined the</p>
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<p>1 oxidized.</p> <p>2 A. There's so many variables in the human</p> <p>3 body, it's impossible to know when a mesh, at what</p> <p>4 point it oxidizes to the point of degradation to be</p> <p>5 an issue.</p> <p>6 Q. Doctor, can you identify by name one</p> <p>7 person who has had their mesh surgery removed</p> <p>8 because of degradation?</p> <p>9 MR. JACKSON: Objection, form.</p> <p>10 A. My best is all of them had them, they were</p> <p>11 degraded by oxidation. Every mesh that was removed</p> <p>12 from these women, I'm very confident would show</p> <p>13 evidence of degradation by oxidation. It is because</p> <p>14 of my knowledge of polypropylene oxidation.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. You have never talked to the doctors?</p> <p>17 A. I have not.</p> <p>18 Q. You have never looked at the medical</p> <p>19 records?</p> <p>20 A. That's correct.</p> <p>21 Q. You have never talked to any of these</p> <p>22 plaintiffs?</p> <p>23 A. That's correct.</p> <p>24 Q. Or any of these family members?</p>	<p>1 explant?</p> <p>2 A. Because I understand the chemistry of</p> <p>3 polypropylene, and the fact that it interacts with</p> <p>4 oxidizing species and degrades, and as part of the</p> <p>5 oxidation process, molecular weight is lowered. And</p> <p>6 the fact that they were implanted for a period of</p> <p>7 time, I'm a hundred percent confident that if I had</p> <p>8 a sensitive way to measure molecular weight, or I</p> <p>9 should say applied a sensitive technique for</p> <p>10 measuring molecular weight of all of these explanted</p> <p>11 meshes, I can detect a loss of molecular weight. I</p> <p>12 have full confidence of that.</p> <p>13 Q. A loss of molecular weight means</p> <p>14 degradation has occurred, correct?</p> <p>15 A. That's correct.</p> <p>16 Q. Let's take, for example, Harriet Beach,</p> <p>17 the first named plaintiff. Do you have any evidence</p> <p>18 to confirm that Harriet Beach, her explant, lost</p> <p>19 molecular weight?</p> <p>20 MR. JACKSON: Objection, asked and</p> <p>21 answered.</p> <p>22 A. Do I have data?</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Yes, sir.</p>

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<p>1 A. Other than my knowledge of polypropylene</p> <p>2 oxidation chemistry, no.</p> <p>3 Q. Doctor, do you have data on any of the 23</p> <p>4 plaintiffs that would show their mesh lost molecular</p> <p>5 weight?</p> <p>6 A. I have not actually done the measurements</p> <p>7 to collect the data, no.</p> <p>8 Q. In fact, Doctor, you have not done</p> <p>9 anything according to the scientific method to prove</p> <p>10 whether or not any of these plaintiffs' mesh</p> <p>11 degraded in vivo, have you?</p> <p>12 MR. JACKSON: Objection, form.</p> <p>13 A. I have done a ton of research using the</p> <p>14 scientific method to study the degradation chemistry</p> <p>15 of polypropylene.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. But have you proven that using the</p> <p>18 scientific method for any of these 23 plaintiffs,</p> <p>19 yes or no?</p> <p>20 A. Not those specific samples, no.</p> <p>21 Q. Doctor, are you aware of any peer-reviewed</p> <p>22 literature that shows there is a clinical effect of</p> <p>23 degradation in vivo?</p> <p>24 A. I've read a ton of literature put out in</p>	<p>1 cytotoxic, so that tells me that any dye that exudes</p> <p>2 from the surface in the neighboring tissue would be</p> <p>3 toxic to it.</p> <p>4 Q. Are you offering opinions today to a</p> <p>5 reasonable degree of scientific certainty that</p> <p>6 Prolene is toxic in the human body?</p> <p>7 MR. JACKSON: Objection, form.</p> <p>8 A. No, just that pigment is cytotoxic.</p> <p>9 That's all I can say.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Doctor, as a material scientist, are you</p> <p>12 aware of any material that's completely inert?</p> <p>13 A. Completely inert, about the closest to</p> <p>14 completely inert is diamond.</p> <p>15 Q. Are you aware of any medical device on the</p> <p>16 market that's completely inert?</p> <p>17 A. Again, probably the closest would be</p> <p>18 titanium, but even that is not, completely is a</p> <p>19 pretty, 100.00 percent is completely and there's no</p> <p>20 such thing.</p> <p>21 Q. Doctor, are you aware of any mesh, medical</p> <p>22 device on the market that is inert in the human</p> <p>23 body?</p> <p>24 A. All I can tell you is from reading the</p>
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<p>1 the last ten years on explanted meshes that show</p> <p>2 degradation.</p> <p>3 Q. Doctor, are you aware of any clinical data</p> <p>4 that shows degradation is clinically significant?</p> <p>5 MR. JACKSON: Objection, form.</p> <p>6 A. Clinically, I can't equate to that,</p> <p>7 clinically significant.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. Doctor, are you aware of any clinical data</p> <p>10 that shows degradation causes clinical harm?</p> <p>11 A. Again, since I'm not a medical doctor, I</p> <p>12 can't equate the clinical.</p> <p>13 Q. Are you aware of any data that shows</p> <p>14 degradation causes harm in women?</p> <p>15 A. Any data?</p> <p>16 Q. As a scientist.</p> <p>17 A. Other than reading the scientific</p> <p>18 literature that I've talked about on explants.</p> <p>19 Q. Doctor, have you concluded that Prolene is</p> <p>20 toxic?</p> <p>21 MR. JACKSON: Objection, form.</p> <p>22 A. I know from reading the MSDS sheets on the</p> <p>23 different additives in Prolene, I know that the</p> <p>24 colorant, the copper phthalocyanine pigment is</p>	<p>1 literature, it appears that PDVF is the closest to</p> <p>2 being inert but even that's not inert.</p> <p>3 Q. Thank you. Doctor, when we talked about</p> <p>4 degradation, you will agree that there must be loss</p> <p>5 of molecular weight for degradation to occur?</p> <p>6 MR. JACKSON: Objection, misstates</p> <p>7 the witness' testimony.</p> <p>8 A. No.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. What happens to a polymer when it loses</p> <p>11 molecular weight, does it degrade?</p> <p>12 A. Yes.</p> <p>13 Q. There must be loss of molecular weight for</p> <p>14 degradation to have occurred, correct?</p> <p>15 A. No.</p> <p>16 Q. Why not?</p> <p>17 A. There's intermediate species like, for</p> <p>18 example, before molecular weight loss occurs, there</p> <p>19 is generally oxidation. There's a hydroperoxide</p> <p>20 chemical functionality on the polymer and that</p> <p>21 precedes molecular weight loss.</p> <p>22 Q. But for oxidation to have occurred, there</p> <p>23 must be loss of molecular weight, correct?</p> <p>24 A. No.</p>

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<p>1 Q. Why not?</p> <p>2 A. The additives oxidize so they are</p> <p>3 constantly dynamic, changing in their structure. As</p> <p>4 I mentioned earlier, the DLTDP changes to a sulfone,</p> <p>5 ultimately to a sulfoxide. That's an oxidized</p> <p>6 species, so it is changing --</p> <p>7 Q. I'm not asking about --</p> <p>8 MR. WALLACE: Chad, you have to let</p> <p>9 him finish. This has been going on for a</p> <p>10 while. Just let him finish. We have</p> <p>11 been good all day.</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. Let's talk about oxidation.</p> <p>14 A. Okay.</p> <p>15 Q. For oxidation to occur, there must be a</p> <p>16 chain scission in the cleavage of the polymer chain,</p> <p>17 correct?</p> <p>18 A. No, just to explain, you can have</p> <p>19 oxidation going on of the additives of the polymer</p> <p>20 chain without degradation that precedes molecular</p> <p>21 weight loss.</p> <p>22 Q. If a polymer oxidizes, will there be loss</p> <p>23 of molecular weight?</p> <p>24 MR. JACKSON: Objection, asked and</p>	<p>1 MR. JACKSON: Objection, form.</p> <p>2 A. No. As I mentioned earlier, you can have</p> <p>3 oxidation without chain scission.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. If oxidation occurs, you always have</p> <p>6 reduced physical properties of the polymer?</p> <p>7 MR. JACKSON: Objection, form.</p> <p>8 A. In the early stages, it's probably</p> <p>9 non-detectable.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. If oxidation occurs, you will have</p> <p>12 embrittlement?</p> <p>13 A. Ultimately.</p> <p>14 Q. If oxidation occurs, you will have loss of</p> <p>15 tensile strength?</p> <p>16 A. Ultimately.</p> <p>17 Q. If oxidation occurs, you will have loss of</p> <p>18 elongation?</p> <p>19 A. That's dependent. If body fluids, lipids,</p> <p>20 oils, fats are absorbed into the polymer, it</p> <p>21 actually increases elongation.</p> <p>22 Q. You will have loss of toughness if</p> <p>23 oxidation occurs, correct?</p> <p>24 MR. JACKSON: Objection, form.</p>
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<p>1 answered.</p> <p>2 A. There can be, but there doesn't</p> <p>3 necessarily have to be.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. If oxidation occurs, will there be strong</p> <p>6 carbonyl bands on the FTIR?</p> <p>7 A. Again, that's a later stage. The</p> <p>8 hydroperoxide group that forms first is not a</p> <p>9 carbonyl. You don't see an FTIR carbonyl band.</p> <p>10 If it changes to another species, then it</p> <p>11 generates a carbonyl band. But the first stage of</p> <p>12 oxidation is generated to a hydroperoxide. That's</p> <p>13 still oxidation, but it hasn't formed a carbonyl</p> <p>14 band yet.</p> <p>15 Q. At what point does a loss of molecular</p> <p>16 weight occur in oxidation?</p> <p>17 A. At the point that the hydroperoxide group</p> <p>18 changes to a carbonyl, it is accompanied by chain</p> <p>19 scission and you lose molecular weight.</p> <p>20 Q. So when you have chain scission, you lose</p> <p>21 molecular weight?</p> <p>22 A. That's correct.</p> <p>23 Q. For oxidation to occur, you must always</p> <p>24 have chain scission of the polymer chain, correct?</p>	<p>1 A. Depends on how you define toughness, but</p> <p>2 generally, yes.</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. Let's define it as the area under the</p> <p>5 curve on a stress-strain diagram. With that</p> <p>6 definition, you will have a loss of toughness,</p> <p>7 correct?</p> <p>8 A. Give me a minute to think about that.</p> <p>9 Yes.</p> <p>10 Q. Doctor, would you ever expect to see an</p> <p>11 increase in physical properties in a polymer that is</p> <p>12 oxidized?</p> <p>13 A. Which physical property?</p> <p>14 Q. Tensile strength.</p> <p>15 A. Yes.</p> <p>16 Q. Young's modulus?</p> <p>17 A. Can I explain? Tensile strength, as a</p> <p>18 material becomes more brittle, generally increases.</p> <p>19 Young's modulus, if there's no chemicals absorbed</p> <p>20 into the material to alter its plastic nature,</p> <p>21 Young's modulus will generally increase as the</p> <p>22 material embrittles.</p> <p>23 Q. What about toughness?</p> <p>24 A. Toughness generally decreases even though</p>

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<p>1 the tensile strength -- of course, you are getting</p> <p>2 into some issues here which require a lot of</p> <p>3 materials science explanations. But in general, as</p> <p>4 materials embrittle, the Young's modulus and the</p> <p>5 tensile strength actually increase but the area</p> <p>6 under the stress-strain curve decreases.</p> <p>7 Q. Doctor, are you aware of any product on</p> <p>8 the market --</p> <p>9 MR. HUTCHINSON: We are going to</p> <p>10 have to take a quick break, and this</p> <p>11 obviously does not count as my time. We</p> <p>12 are going to have to take a quick break</p> <p>13 because of the noise outside.</p> <p>14 THE VIDEOGRAPHER: We are off the</p> <p>15 video record. The time is 11:33 a.m.</p> <p>16 (Recess.)</p> <p>17 THE VIDEOGRAPHER: We are back on</p> <p>18 the video record. The time is 11:33 a.m.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. Doctor, are you aware of any medical</p> <p>21 product on the market that will never oxidize?</p> <p>22 A. No.</p> <p>23 Q. Doctor, can oxidation of pelvic Prolene</p> <p>24 mesh -- strike that.</p>	<p>1 sitting here today what the safer alternative for</p> <p>2 Prolene would be?</p> <p>3 MR. JACKSON: Objection, asked and</p> <p>4 answered.</p> <p>5 A. Well, I know from my experience as a</p> <p>6 polymer scientist, I have worked with PVDF. It is</p> <p>7 used in water filtration membranes, and the reason</p> <p>8 is because it's like a rock when it comes to</p> <p>9 oxidative stability.</p> <p>10 They actually clean these membranes by</p> <p>11 soaking them in concentrated bleach for several days</p> <p>12 to burn off the organics. And yet even though it</p> <p>13 tolerates that for a while, eventually even those</p> <p>14 membranes eventually oxidize and degrade and have to</p> <p>15 be replaced.</p> <p>16 Q. And there are risks associated with PVDF,</p> <p>17 correct?</p> <p>18 MR. JACKSON: Objection, form.</p> <p>19 A. Risks?</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Yes, medical risks associated with PVDF,</p> <p>22 correct?</p> <p>23 MS. FITZPATRICK: You can't just put</p> <p>24 an expert up here and ask anything that</p>
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<p>1 Can oxidation of Prolene pelvic mesh ever</p> <p>2 be completely eliminated in vivo?</p> <p>3 MR. JACKSON: Objection, form.</p> <p>4 A. No.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Doctor, you talked about a PVDF earlier;</p> <p>7 is that correct?</p> <p>8 A. Yes.</p> <p>9 Q. Is that what you believe would have been a</p> <p>10 safer alternative than polypropylene?</p> <p>11 MR. JACKSON: Objection, form.</p> <p>12 A. I have no basis to make that kind of a</p> <p>13 conclusion other than my understanding of the</p> <p>14 relative oxidative stability of PVDF versus</p> <p>15 polypropylene.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Doctor, what in your opinion is a safer</p> <p>18 alternative for Prolene in pelvic floor repair?</p> <p>19 MR. JACKSON: Objection, form.</p> <p>20 A. I'm not here to opine on that. I was just</p> <p>21 asked to talk about polypropylene meshes. So I'd</p> <p>22 rather not get into that kind of a discussion.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. I understand, but do you have an opinion</p>	<p>1 you want. So if it is tied to his</p> <p>2 report, fine; but other than that, you</p> <p>3 are going to have to move on.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Can you answer that question?</p> <p>6 A. Repeat the question.</p> <p>7 Q. Yes. Are you aware of any medical risks</p> <p>8 using PVDF as a medical device?</p> <p>9 MS. FITZPATRICK: I am going to</p> <p>10 instruct the witness not to answer unless</p> <p>11 you can show for some reason it is in his</p> <p>12 report.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. Doctor, have you ever tested the</p> <p>15 durability of PVDF as a mesh material inside the</p> <p>16 human body?</p> <p>17 MS. FITZPATRICK: Same objection,</p> <p>18 same instruction.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. Doctor, would you ever guarantee, would</p> <p>21 you ever provide a lifetime guarantee for PVDF mesh?</p> <p>22 MR. JACKSON: Same instruction, same</p> <p>23 objection.</p> <p>24 BY MR. HUTCHINSON:</p>

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<p>1 Q. Doctor, are you aware of any mesh made, on</p> <p>2 the market made out of PVDF?</p> <p>3 MS. FITZPATRICK: Objection, same</p> <p>4 instruction.</p> <p>5 MR. HUTCHINSON: Instructing the</p> <p>6 witness not to answer?</p> <p>7 MS. FITZPATRICK: I am. You want to</p> <p>8 show us why you think that's in his</p> <p>9 report, I'd be happy to reconsider and</p> <p>10 look at it; but otherwise, just having an</p> <p>11 expert witness sitting in the chair and</p> <p>12 having him opine on things that are well</p> <p>13 beyond his report is not appropriate.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Doctor, could you tell us what would be a</p> <p>16 reasonably safe alternative to Prolene mesh?</p> <p>17 MR. JACKSON: Objection to form.</p> <p>18 A. Not without investigating and researching</p> <p>19 that question.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Doctor, have you done any efforts to</p> <p>22 research or investigate that question?</p> <p>23 A. A safer alternative, no. That's beyond</p> <p>24 the scope of what I was asked to do.</p>	<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Doctor, turn with me to the last page of</p> <p>3 the seven-year dog study marked as Exhibit 9 to your</p> <p>4 deposition. Are you there with me?</p> <p>5 A. Yes.</p> <p>6 Q. Have you ever seen this particular page</p> <p>7 before?</p> <p>8 A. Absolutely, yes.</p> <p>9 Q. Did you look at the breaking strength,</p> <p>10 elongation and Young's modulus for Prolene?</p> <p>11 A. I certainly did.</p> <p>12 Q. Doctor, what did you notice about it?</p> <p>13 A. I noticed the Young's modulus was</p> <p>14 ridiculously low after seven years.</p> <p>15 Q. Doctor, do you have any reason to believe</p> <p>16 that the negative 70 shown for Prolene is incorrect?</p> <p>17 A. No.</p> <p>18 Q. Doctor, do you have any reason to believe</p> <p>19 that the 111 percent increase of elongation for</p> <p>20 Prolene is incorrect?</p> <p>21 A. No.</p> <p>22 Q. What about for the breaking strength of</p> <p>23 negative 5 percent, any reason to believe that's</p> <p>24 incorrect?</p>
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<p>1 Q. Doctor, what's your opinion about what</p> <p>2 Ethicon should have done differently to prevent</p> <p>3 oxidation of Prolene?</p> <p>4 MR. JACKSON: Objection, form.</p> <p>5 A. There is no technology that I'm aware of</p> <p>6 where you can prevent the oxidation of</p> <p>7 polypropylene.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. Doctor, if we talk about the physical</p> <p>10 properties of mesh, have you read the seven-year dog</p> <p>11 study?</p> <p>12 A. I have indeed.</p> <p>13 (Priddy Deposition Exhibit 9 was</p> <p>14 marked for identification.)</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. I want to hand you what we'll mark as</p> <p>17 Exhibit 9 to your deposition.</p> <p>18 (Witness reviewing document.)</p> <p>19 Q. Doctor, this is the seven-year Burkley dog</p> <p>20 study that you relied on?</p> <p>21 A. Yes.</p> <p>22 MR. JACKSON: I am just going to</p> <p>23 object because it says Barbolt on the</p> <p>24 cover. You said Burkley.</p>	<p>1 A. No.</p> <p>2 Q. Doctor, have you ever done any type of</p> <p>3 analysis using this data from the dog study?</p> <p>4 A. Yes.</p> <p>5 Q. For Prolene?</p> <p>6 A. Yes.</p> <p>7 Q. Is it included in your report?</p> <p>8 A. No.</p> <p>9 Q. Why not?</p> <p>10 A. If I do a supplemental report, I'll</p> <p>11 probably include it, but I didn't include it in this</p> <p>12 report.</p> <p>13 Q. Why not?</p> <p>14 A. I can't answer the question. I just</p> <p>15 didn't do it.</p> <p>16 Q. Did the lawyers that hired you instruct</p> <p>17 you not to include that in your supplemental report?</p> <p>18 MR. JACKSON: Objection, form.</p> <p>19 BY MR. HUTCHINSON:</p> <p>20 Q. I mean in your original report.</p> <p>21 A. No.</p> <p>22 Q. But you are currently working on</p> <p>23 evaluating this data, is that your testimony?</p> <p>24 A. No, I just said I have evaluated it.</p>

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<p>1 Q. Are you currently doing an analysis using</p> <p>2 this type of data?</p> <p>3 MR. JACKSON: Objection, asked and</p> <p>4 answered.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Currently?</p> <p>7 A. No, I have analyzed this data.</p> <p>8 Q. But I thought you said you have done some</p> <p>9 tests that are not included in the report.</p> <p>10 MR. JACKSON: Objection, misstates</p> <p>11 witness' testimony.</p> <p>12 A. I have in the past, yes. I have done</p> <p>13 quite a few tests.</p> <p>14 Q. What type of tests of the breaking</p> <p>15 strength, elongation and Young's modulus of Prolene</p> <p>16 have you done?</p> <p>17 A. I haven't done tests, I have evaluated</p> <p>18 this data.</p> <p>19 Q. Doctor, does this data that we are looking</p> <p>20 at now support your opinions that Prolene degrades?</p> <p>21 A. Absolutely.</p> <p>22 Q. How so?</p> <p>23 A. The 70 percent loss of modulus, that's</p> <p>24 huge.</p>	<p>1 Doctor?</p> <p>2 A. No.</p> <p>3 Q. Why not?</p> <p>4 A. I focused on the other issues and didn't</p> <p>5 include that.</p> <p>6 Q. You will agree that the physical</p> <p>7 properties that are shown of the Prolene sutures in</p> <p>8 the dog study improved after seven years?</p> <p>9 A. Absolutely not, no. Loss of modulus is</p> <p>10 huge. That means the material has no integrity. If</p> <p>11 it had been any stress at all on it, it would have</p> <p>12 stretched right out.</p> <p>13 (Priddy Deposition Exhibit 10 was</p> <p>14 marked for identification.)</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. Doctor, I want to hand you what we will</p> <p>17 mark as Exhibit 10 to your deposition. This shows</p> <p>18 toughness as the area under the curve, correct?</p> <p>19 MR. JACKSON: Objection, form.</p> <p>20 Q. The stress-strain chart.</p> <p>21 (Witness reviewing document.)</p> <p>22 A. Yes.</p> <p>23 Q. Doctor, these are the same plots or the</p> <p>24 same data that we saw from the Burkley dog study</p>
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<p>1 Q. That means Young's modulus is stiffness,</p> <p>2 correct?</p> <p>3 A. Yes, it does.</p> <p>4 Q. And Young's modulus -- strike that.</p> <p>5 This means that the Prolene lost</p> <p>6 70 percent of its stiffness after seven years?</p> <p>7 A. That's correct.</p> <p>8 Q. And why do you believe that supports your</p> <p>9 opinion?</p> <p>10 A. Going from a 700,000 modulus down to</p> <p>11 200,000, I took that data and plotted it out. So I</p> <p>12 took the tensile, the Young's modulus which is</p> <p>13 tensile modulus times 0 after one year, after two</p> <p>14 years, after seven years, plotted it. It's a</p> <p>15 straight line, with 98 percent statistical linear</p> <p>16 straight line. When I extrapolate that until the</p> <p>17 time it hits 0 modulus, it predicts ten years, three</p> <p>18 more years, that material would have been water.</p> <p>19 A stiffness of 200,000 modulus is, the</p> <p>20 Prolene, if it had been held up, it would have</p> <p>21 sagged. There's no stiffness whatsoever, no</p> <p>22 integrity. It would have been like jello. That's</p> <p>23 huge.</p> <p>24 Q. Is that information in your expert report,</p>	<p>1 that we just looked at, correct?</p> <p>2 A. I don't know.</p> <p>3 Q. Why don't you compare the data on this</p> <p>4 chart to the data on the last page of the seven-year</p> <p>5 dog study.</p> <p>6 A. These stress-strain curves look strange.</p> <p>7 I would have to actually see the plot-outs from the</p> <p>8 instruments that ran this stress-strain curve</p> <p>9 because you normally don't get a 0 point and a point</p> <p>10 up here that's a perfect straight line. It's always</p> <p>11 an arc.</p> <p>12 So it looks like somebody took a ruler and</p> <p>13 hand-drew this out. It doesn't look right.</p> <p>14 Q. Doctor, looking at the red at time 0,</p> <p>15 elongation was 1.68 pounds according to the Burkley</p> <p>16 dog study, correct?</p> <p>17 A. That's percent.</p> <p>18 Q. I'm sorry, percent.</p> <p>19 A. Right.</p> <p>20 Q. Elongation times 0 is 37 percent; is that</p> <p>21 right?</p> <p>22 A. Again, this data doesn't look -- something</p> <p>23 is wrong with the data.</p> <p>24 Q. What's wrong with the data?</p>

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<p>1 A. I mean, elongation is not to pounds, it's</p> <p>2 in percent and above it you have got 37 percent. I</p> <p>3 mean, that looks correct, year 0, 37 percent. It</p> <p>4 must be the breaking strength is 1.68 pounds. Okay,</p> <p>5 now I understand.</p> <p>6 Q. Now that you have looked at it, you will</p> <p>7 agree that the data is correct on Exhibit 10?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. Well, again, I can't make that leap.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Why not?</p> <p>12 A. As I say, the curves look weird. It looks</p> <p>13 like somebody hand-drew with a ruler. The plot-outs</p> <p>14 from a tensile, an Instron, don't look like this.</p> <p>15 They are not "blocky" like this. They are nice,</p> <p>16 smooth curves. Somebody has taken the data and</p> <p>17 hand-drawn this.</p> <p>18 Q. Doctor, you will agree that the numbers</p> <p>19 for the breaking strength and elongation at year</p> <p>20 zero are the same as the Burkley dog study, correct?</p> <p>21 A. Hang on.</p> <p>22 (Witness reviewing document.)</p> <p>23 A. Yes.</p> <p>24 MR. JACKSON: Chad, are you asking</p>	<p>1 Q. Thank you. And Doctor, you will agree</p> <p>2 that the area under the curve is a measure of</p> <p>3 toughness, correct?</p> <p>4 MR. JACKSON: Objection, form.</p> <p>5 A. As I say, there's something wrong here.</p> <p>6 What I'm seeing here with modulus does not equate to</p> <p>7 what I'm seeing here (indicating). There's</p> <p>8 something wrong.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. But can you tell us sitting here today</p> <p>11 what's wrong?</p> <p>12 A. What I'm saying, modulus is listed here.</p> <p>13 It's not reflected here (indicating). There's a</p> <p>14 problem. Something is wrong.</p> <p>15 Q. I understand. My question is: Sitting</p> <p>16 here today, can you tell us what is wrong?</p> <p>17 MR. JACKSON: Objection, asked and</p> <p>18 answered.</p> <p>19 A. I can't. I have to figure it out. I</p> <p>20 cannot figure it out based on what I'm seeing. It</p> <p>21 just doesn't equate, is what I'm saying. There's</p> <p>22 something, there's a problem.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Have you made any efforts to determine</p>
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<p>1 him to compare data in Exhibit 9 and</p> <p>2 Exhibit 10? Is that what you are asking</p> <p>3 him?</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. I'm sorry, did you say yes?</p> <p>6 A. Yes, I did.</p> <p>7 THE WITNESS: That was what I assume</p> <p>8 he was asking.</p> <p>9 Q. And Doctor, at year 7 --</p> <p>10 MS. FITZPATRICK: Chad, can he</p> <p>11 answer the question so it is clear on the</p> <p>12 record?</p> <p>13 MR. JACKSON: Chad, I just asked,</p> <p>14 were you asking Dr. Priddy to compare</p> <p>15 Exhibit 9 and Exhibit 10? Is that what</p> <p>16 you just asked him to do?</p> <p>17 MR. HUTCHINSON: Yes, I did. I</p> <p>18 thought the witness answered your</p> <p>19 question. My bad.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Doctor, at year 7, is the data on</p> <p>22 Exhibit 10 the same as the data in the Burkley dog</p> <p>23 study?</p> <p>24 A. Yes, it is.</p>	<p>1 what that problem is?</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A. Until I just noticed the problem now, no.</p> <p>4 I should say yes, I have been trying to figure it</p> <p>5 out the last five minutes and I can't. It doesn't</p> <p>6 add up.</p> <p>7 I've done literally thousands of</p> <p>8 stress-strain tensile studies on different samples</p> <p>9 and this doesn't look right. Something's wrong.</p> <p>10 Can I interject something at this point?</p> <p>11 It's not an answer to a question, it is kind of</p> <p>12 answering your question.</p> <p>13 Modulus is slope. There's a huge</p> <p>14 difference between a slope of a Young's modulus of</p> <p>15 200,000 and 700,000.</p> <p>16 These two curves have almost the same</p> <p>17 slope, and this does not reflect a difference of 200</p> <p>18 to 700,000. As I say, something is clearly wrong.</p> <p>19 Q. Doctor, can you quantify the rate at which</p> <p>20 you believe antioxidants are depleted from Prolene?</p> <p>21 MR. JACKSON: Objection, asked and</p> <p>22 answered.</p> <p>23 A. In which?</p> <p>24 BY MR. HUTCHINSON:</p>

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<p>1 Q. In vivo.</p> <p>2 A. It's too many variables. It's impossible.</p> <p>3 It's going to be dependent upon the amount of</p> <p>4 tension, the amount of inflammation, the amount of</p> <p>5 oxidizing species, but the foreign body response,</p> <p>6 there's too many variables, plus you've got the</p> <p>7 variability in the mesh and its oxidative stability.</p> <p>8 So you just can't predict that.</p> <p>9 Q. Have you made any efforts to test that</p> <p>10 whatsoever?</p> <p>11 MR. JACKSON: Objection, form.</p> <p>12 A. Test the rate at which it would, just my</p> <p>13 OIT work.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Doctor, you agree that sutures, Prolene</p> <p>16 sutures have been on the market for a long time?</p> <p>17 A. Yes.</p> <p>18 Q. Doctor, are you criticizing Ethicon's</p> <p>19 Prolene sutures in any way?</p> <p>20 A. I was not asked to opine on that.</p> <p>21 Q. Do you have any criticisms of Ethicon's</p> <p>22 sutures?</p> <p>23 MR. JACKSON: Objection, asked and</p> <p>24 answered.</p>	<p>1 oxidized mesh in their body?</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A. Yes.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Doctor, is it your opinion that every</p> <p>6 medical doctor who uses Prolene in the body is</p> <p>7 committing malpractice?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. I'm not going to go there. I'm a plastics</p> <p>10 scientist. I'm not into that kind of stuff.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q. Do you believe that every medical doctor</p> <p>13 who is implanting Prolene in the body is doing</p> <p>14 something wrong?</p> <p>15 A. They are probably relying upon the</p> <p>16 literature provided to them by Ethicon that said</p> <p>17 it's safe and effective and they are just relying on</p> <p>18 that, I presume.</p> <p>19 Q. My question to you, though, is: Do you</p> <p>20 believe that doctors who implant Prolene in the body</p> <p>21 are doing something wrong?</p> <p>22 MR. JACKSON: Objection, asked and</p> <p>23 answered.</p> <p>24 MS. FITZPATRICK: Beyond the scope</p>
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<p>1 A. Again, I wasn't -- I haven't even thought</p> <p>2 about that.</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. Doctor, have you thought about whether or</p> <p>5 not sutures made out of Prolene oxidize in the body?</p> <p>6 A. If they are made out of polypropylene,</p> <p>7 they oxidize in the body. That's a given.</p> <p>8 Q. Doctor, do you know if Ethicon's sutures</p> <p>9 were approved by FDA as safe and effective?</p> <p>10 A. I remember reading they were approved by</p> <p>11 FDA.</p> <p>12 Q. Doctor, is it your opinion that every</p> <p>13 person who has a Prolene suture implanted in their</p> <p>14 body has an oxidized product in their body?</p> <p>15 A. Of course, yes, I am.</p> <p>16 Q. What about hernia mesh? Do you know how</p> <p>17 long hernia mesh has been on the market?</p> <p>18 A. I don't know precisely. I know a long</p> <p>19 time.</p> <p>20 Q. Is it your opinion that Prolene hernia</p> <p>21 mesh oxidizes in the body?</p> <p>22 A. Yes.</p> <p>23 Q. And it is your opinion that every person</p> <p>24 who has ever received a hernia mesh implant has</p>	<p>1 of his opinions.</p> <p>2 A. How can I opine on that? That's beyond</p> <p>3 my, what I'm asked to do here.</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Can you answer that question?</p> <p>6 A. I'd rather not. That's an opinion outside</p> <p>7 my area of expertise.</p> <p>8 Q. Can you answer that question?</p> <p>9 A. Can I answer it? I can give you an</p> <p>10 opinion for what it's worth.</p> <p>11 MR. JACKSON: All asked and</p> <p>12 answered.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. What's your opinion?</p> <p>15 A. Are they doing something wrong?</p> <p>16 Q. Yes, by using Prolene in the body as an</p> <p>17 implant?</p> <p>18 MR. JACKSON: Objection, this is</p> <p>19 outside the scope of the report.</p> <p>20 A. I don't think the doctor is doing anything</p> <p>21 wrong. He is just relying upon the information he</p> <p>22 has, his best judgment. I think Ethicon is doing</p> <p>23 something wrong but the doctor isn't doing anything</p> <p>24 wrong.</p>

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<p>1 MR. HUTCHINSON: Move to strike as</p> <p>2 non-responsive.</p> <p>3 MR. WALLACE: Move to strike because</p> <p>4 you don't like his answer.</p> <p>5 MS. FITZPATRICK: How is that</p> <p>6 non-responsive?</p> <p>7 MR. WALLACE: All right, we are</p> <p>8 close to done.</p> <p>9 MR. HUTCHINSON: How much longer do</p> <p>10 we have?</p> <p>11 THE VIDEOGRAPHER: 20 minutes.</p> <p>12 MR. WALLACE: We may have some</p> <p>13 questions so you might want to reserve a</p> <p>14 couple minutes if you need it.</p> <p>15 BY MR. HUTCHINSON:</p> <p>16 Q. Doctor, let's go back to your expert</p> <p>17 report on Page 15. Are you there with me?</p> <p>18 A. I am there, yes.</p> <p>19 Q. Doctor, are these charts, say, for</p> <p>20 example, the chart on Page 15.</p> <p>21 A. Yes.</p> <p>22 Q. What do you call these charts?</p> <p>23 A. OIT curves.</p> <p>24 Q. Curves. Doctor, would you expect the</p>	<p>1 MR. JACKSON: Objection, form.</p> <p>2 A. Signs?</p> <p>3 BY MR. HUTCHINSON:</p> <p>4 Q. Do you see any signs --</p> <p>5 A. I would say it's an indication that they</p> <p>6 are reacting, yes, they are oxidizing.</p> <p>7 Q. Just so the record is clear, what are you</p> <p>8 referring to specifically?</p> <p>9 A. The slight, gradual elevation here is</p> <p>10 probably due to the antioxidants oxidizing,</p> <p>11 probably.</p> <p>12 Q. That's at the curve, the DSC curve on the</p> <p>13 top of Page 15, correct?</p> <p>14 A. Yes.</p> <p>15 Q. Doctor, do you have any opinion regarding</p> <p>16 the specific concentration level of Santonox R and</p> <p>17 DLTDP that should have been in Prolene?</p> <p>18 A. Just based upon the data sheet I was</p> <p>19 provided that gave me a target loading level.</p> <p>20 Q. Right, but do you have an opinion about</p> <p>21 Ethicon's Prolene, about what the specific</p> <p>22 concentration level of Santonox R and DLTDP should</p> <p>23 have been?</p> <p>24 MR. JACKSON: Objection, asked and</p>
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<p>1 additives in Prolene to have an exothermic peak?</p> <p>2 A. They will, but it's going to be barely</p> <p>3 detectable.</p> <p>4 Q. Why would it be barely detectable?</p> <p>5 A. Excuse me, I got to sneeze.</p> <p>6 Because they are there in such low</p> <p>7 concentration relative to the polymer that like,</p> <p>8 when, for example, the DLTDP is oxidized from the</p> <p>9 sulfur or the sulfide to the sulfone, ultimately to</p> <p>10 the sulfoxide, that's an exothermic reaction. But</p> <p>11 the DLTDP is such low concentration, the instrument</p> <p>12 is not sensitive enough to detect it. So you get a</p> <p>13 slight elevation in the baseline.</p> <p>14 This curve is not -- if I was to draw a</p> <p>15 perfectly horizontal line, you would see this</p> <p>16 deviating up slightly. That's probably the Santonox</p> <p>17 R and the DLTDP slowly oxidizing, but you really</p> <p>18 don't see a significant response until they are</p> <p>19 depleted and the polypropylene takes over.</p> <p>20 Q. Is that the signs of the additives that</p> <p>21 you are seeing in your thermogram data?</p> <p>22 A. Excuse me?</p> <p>23 Q. Is that the signs of the additives that</p> <p>24 you are seeing in your thermogram data?</p>	<p>1 answered.</p> <p>2 A. Should have been for the Prolene</p> <p>3 application?</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q. Yes, sir.</p> <p>6 A. My opinion is, it's not appropriate to use</p> <p>7 polypropylene, stabilized polypropylene with those</p> <p>8 additives in for that application. It's not</p> <p>9 appropriate.</p> <p>10 Q. Can you tell us what additives if not</p> <p>11 Santonox R and DLTDP, can you tell us what</p> <p>12 antioxidants should have been used?</p> <p>13 A. Let me restate. I do not know of any</p> <p>14 antioxidant stabilizer formulation that's totally</p> <p>15 non-extractable by oils and fats in the body that</p> <p>16 you could put into polypropylene and guarantee that</p> <p>17 it's going to last for decades in the body because</p> <p>18 they are going to be extracted from the surface. It</p> <p>19 is just a given basic polymer science.</p> <p>20 Q. Can you tell the ladies and gentlemen of</p> <p>21 the jury what additives, specific additives should</p> <p>22 have been used if not Santonox R and DLTDP?</p> <p>23 MR. JACKSON: Objection, asked and</p> <p>24 answered.</p>

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<p>1 A. Again, I do not believe it's possible to</p> <p>2 stabilize polypropylene with any additives to make</p> <p>3 an implantable mesh product that would last for</p> <p>4 decades, just not going to happen.</p> <p>5 MR. HUTCHINSON: I want to take just</p> <p>6 a quick break, go off the record.</p> <p>7 THE VIDEOGRAPHER: We are off the</p> <p>8 video record. The time is 12:01 p.m.</p> <p>9 (Recess.)</p> <p>10 THE VIDEOGRAPHER: We are back on</p> <p>11 the video record. The time is 12:04 p.m.</p> <p>12 BY MR. HUTCHINSON:</p> <p>13 Q. Doctor, have you understood all my</p> <p>14 questions so far?</p> <p>15 A. Yes.</p> <p>16 Q. Is there anything about the testimony that</p> <p>17 you have given you would like to change?</p> <p>18 MR. JACKSON: Objection, form.</p> <p>19 A. Not at this point.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Has a court ever determined that you could</p> <p>22 not give an expert opinion?</p> <p>23 A. That I could not?</p> <p>24 Q. Yes.</p>	<p>1 And I made the analogy of napalm. The</p> <p>2 judge said that wasn't acceptable.</p> <p>3 Q. Doctor, on this DSC curve at the top of</p> <p>4 Page 15.</p> <p>5 A. Yes.</p> <p>6 Q. Is oxidation showing as a smooth</p> <p>7 transition from time 0?</p> <p>8 MR. JACKSON: Objection, form.</p> <p>9 A. On this one?</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Yes.</p> <p>12 A. Yes, that's typical, that's a smooth,</p> <p>13 normal transition, yes.</p> <p>14 Q. But you would say that that is showing a</p> <p>15 smooth transition?</p> <p>16 A. Yes.</p> <p>17 Q. Did you do any resampling?</p> <p>18 A. Any what?</p> <p>19 Q. Resampling?</p> <p>20 MR. JACKSON: Objection, form.</p> <p>21 A. Yes, I had duplicates on a couple samples</p> <p>22 run, yes.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Did you do any retesting?</p>
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<p>1 A. Yes.</p> <p>2 Q. How many times?</p> <p>3 A. Twice that I'm aware of.</p> <p>4 Q. In what circumstances?</p> <p>5 A. One was a patent infringement matter</p> <p>6 involving, against Nike for a shoe sole design and</p> <p>7 because I had never designed shoe soles and didn't</p> <p>8 really have experience working with shoes or shoe</p> <p>9 soles, they deemed my testimony was not admissible.</p> <p>10 And the other time was a portion of my</p> <p>11 testimony was deemed as being not admissible.</p> <p>12 Q. In what particular instance?</p> <p>13 A. See, that was Jarden versus Hearthmark, et</p> <p>14 al. Do you want to know the details of that?</p> <p>15 Q. Yes.</p> <p>16 A. Okay, it involved a company that decided</p> <p>17 to use hand sanitizer, this gel that we squirt from</p> <p>18 a bottle on our hands to sanitize them, to market</p> <p>19 that as a fire starter. So they used a bottle made</p> <p>20 out of PVC to dispense that and a child was using it</p> <p>21 to ignite a fire. And the flame came up the stream</p> <p>22 of gel as it was squirting out of the bottle,</p> <p>23 entered into the bottle, the bottle exploded and</p> <p>24 blew flaming gel all over him.</p>	<p>1 A. Retesting, I had the same mesh run a</p> <p>2 couple times, yes.</p> <p>3 Q. But did you do any retesting of that</p> <p>4 particular DSC curve?</p> <p>5 A. I don't understand what you are asking me.</p> <p>6 Q. Did you do the test again to see if you</p> <p>7 could generate the same curve?</p> <p>8 A. Oh, yes.</p> <p>9 MR. HUTCHINSON: I don't have</p> <p>10 anything further.</p> <p>11 MR. JACKSON: We'll just take about</p> <p>12 five minutes.</p> <p>13 THE VIDEOGRAPHER: We are off the</p> <p>14 video record. The time is 12:07 p.m.</p> <p>15 (Recess.)</p> <p>16 THE VIDEOGRAPHER: We are back on</p> <p>17 the video record. The time is 12:20 p.m.</p> <p>18 MR. JACKSON: I just want to note on</p> <p>19 the record that Dr. Priddy said that the</p> <p>20 materials that were available to him in</p> <p>21 this case were on the flash drive. They</p> <p>22 are not on that drive. We can provide</p> <p>23 those later if needed.</p> <p>24 MR. HUTCHINSON: I'm sorry?</p>

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<p>1 MR. JACKSON: The literature and the</p> <p>2 Ethicon documents are not on there, just</p> <p>3 his work papers.</p> <p>4 MR. HUTCHINSON: This may be, where</p> <p>5 is the literature and documents?</p> <p>6 MR. WALLACE: Since they were your</p> <p>7 documents, we typically don't include</p> <p>8 those, but if you want them, we'll give</p> <p>9 them to you. Typically, you guys don't</p> <p>10 like to be bothered with your own</p> <p>11 documents. That was the issue.</p> <p>12 MR. HUTCHINSON: That was the reason</p> <p>13 they weren't included on the flash drive?</p> <p>14 MR. WALLACE: Yes. I think we have</p> <p>15 done that before.</p> <p>16 EXAMINATION</p> <p>17 BY MR. JACKSON:</p> <p>18 Q. Dr. Priddy, do you remember being asked</p> <p>19 some questions earlier about your work with AMS?</p> <p>20 A. Yes.</p> <p>21 Q. You were a fact witness in AMS?</p> <p>22 A. I was, yes.</p> <p>23 Q. You were not an expert?</p> <p>24 MR. HUTCHINSON: Objection, leading.</p>	<p>1 Q. You interact with people like Steve</p> <p>2 Johnson all the time in your professional career?</p> <p>3 A. I do. I use laboratories all over the US</p> <p>4 and he is one of the, he's the lab I use for OIT.</p> <p>5 Depending on the core area of expertise of the lab,</p> <p>6 I will use different labs for different types of</p> <p>7 testing. I always use Steve for OIT and GC-MS</p> <p>8 analysis.</p> <p>9 Q. So you rely on Steve's work regularly?</p> <p>10 MR. HUTCHINSON: Form.</p> <p>11 A. I do.</p> <p>12 MR. HUTCHINSON: Counsel, if you</p> <p>13 will give me a just a second to lodge my</p> <p>14 objection. Form to the last question.</p> <p>15 BY MR. JACKSON:</p> <p>16 Q. Dr. Priddy, when Steve Johnson runs a test</p> <p>17 for you, it is your job to interpret that data?</p> <p>18 A. That's correct.</p> <p>19 MR. HUTCHINSON: Form.</p> <p>20 BY MR. JACKSON:</p> <p>21 Q. And you do that regularly in your</p> <p>22 profession?</p> <p>23 A. I do.</p> <p>24 Q. Do you recall Mr. Hutchinson asking you</p>
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<p>1 A. Correct.</p> <p>2 BY MR. JACKSON:</p> <p>3 Q. You did not give an expert report?</p> <p>4 A. Right.</p> <p>5 Q. Mr. Hutchinson asked you earlier if you</p> <p>6 were an expert in various fields. Do you remember</p> <p>7 that?</p> <p>8 A. Yes.</p> <p>9 Q. What did you understand that word expert</p> <p>10 to mean to you?</p> <p>11 A. That that was my primary job function of,</p> <p>12 specific area of expertise he was mentioning.</p> <p>13 Q. But just because you said you are not an</p> <p>14 expert in a particular area doesn't mean you don't</p> <p>15 have knowledge and expertise in that area?</p> <p>16 MR. HUTCHINSON: Object, form.</p> <p>17 A. That is correct.</p> <p>18 BY MR. JACKSON:</p> <p>19 Q. Do you remember being asked some questions</p> <p>20 earlier about Steve Johnson?</p> <p>21 A. Yes.</p> <p>22 Q. Steve Johnson is someone who does this</p> <p>23 testing regularly; is that right?</p> <p>24 A. Yes.</p>	<p>1 some questions earlier today about the names of</p> <p>2 various Ethicon products?</p> <p>3 A. Yes.</p> <p>4 Q. Did the names of those products have</p> <p>5 anything to do with your opinions in this case?</p> <p>6 A. No.</p> <p>7 Q. Dr. Priddy, Mr. Hutchinson asked you some</p> <p>8 questions earlier today about Dr. Jordi. Do you</p> <p>9 remember that?</p> <p>10 A. Yes.</p> <p>11 Q. Can you determine anything about Dr.</p> <p>12 Jordi's report without seeing his data?</p> <p>13 A. No.</p> <p>14 Q. Can you evaluate the hypothetical that Mr.</p> <p>15 Hutchinson gave you earlier today without seeing Dr.</p> <p>16 Jordi's data?</p> <p>17 MR. HUTCHINSON: Object to form.</p> <p>18 A. No.</p> <p>19 BY MR. JACKSON:</p> <p>20 Q. Did anything you were asked by Mr.</p> <p>21 Hutchinson today change any of your opinions in this</p> <p>22 case?</p> <p>23 A. No.</p> <p>24 Q. Did anything that Mr. Hutchinson asked you</p>

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<p>1 today change how you view your methodology in this</p> <p>2 case?</p> <p>3 A. No.</p> <p>4 Q. Why didn't you review any plaintiff</p> <p>5 medical records in this case?</p> <p>6 A. It wasn't relative to my opinions, didn't</p> <p>7 affect my opinions.</p> <p>8 Q. Dr. Priddy, you were asked some questions</p> <p>9 earlier about life expectancy of certain products.</p> <p>10 Do you remember that?</p> <p>11 A. Yes.</p> <p>12 Q. Can you explain for the jury why you did</p> <p>13 your testing in this case?</p> <p>14 A. Yes, I was looking specifically at the</p> <p>15 product variability. Normally, when products are</p> <p>16 manufactured, they are manufactured to a</p> <p>17 specification to minimize variability and I just</p> <p>18 wanted to see if these products, these mesh products</p> <p>19 were highly variable in their oxidation resistance</p> <p>20 or if they were all very similar in their oxidation</p> <p>21 resistance.</p> <p>22 Q. Do you remember being asked some questions</p> <p>23 earlier about how blood in the body interacts with</p> <p>24 these products?</p>	<p>1 needs to be done so they don't have failures</p> <p>2 anymore.</p> <p>3 Those are the three main -- it all has to</p> <p>4 do with plastics.</p> <p>5 Q. In your profession, you provide consulting</p> <p>6 services to medical device companies?</p> <p>7 A. I do.</p> <p>8 Q. You have been hired by medical device</p> <p>9 companies to work on implantable medical devices?</p> <p>10 A. Correct.</p> <p>11 Q. You have provided expert testimony on</p> <p>12 behalf of medical companies?</p> <p>13 A. Expert testimony -- most of my work has</p> <p>14 been consulting. I'm trying to think. Of course,</p> <p>15 the AMS work I did, my recollection is they were</p> <p>16 trying to get FDA approval on a mesh product and</p> <p>17 they asked me to opine, to evaluate and opine on the</p> <p>18 usefulness of accelerated laboratory testing of</p> <p>19 their packaging of their device.</p> <p>20 So it wasn't part of a litigation, it was</p> <p>21 part of a petition to the FDA. And I was -- as far</p> <p>22 as being hired by a medical device manufacturer, to</p> <p>23 my knowledge, it's all been consulting work except</p> <p>24 for that.</p>
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<p>1 A. Yes.</p> <p>2 Q. Is it fair that you need to understand how</p> <p>3 chemicals in the body interact with these mesh</p> <p>4 devices to offer your opinions in this case?</p> <p>5 MR. HUTCHINSON: Object to form.</p> <p>6 A. Well, just the fact that knowing that I</p> <p>7 do, that bodies contain chemicals which are fats and</p> <p>8 oils and have the capability to plasticize and</p> <p>9 extract and affect the properties of plastics that</p> <p>10 are implanted in the body, the nature of these</p> <p>11 chemicals, the types of chemicals they are, I</p> <p>12 understand that and how those types of chemicals</p> <p>13 interact with materials. That's all part of my core</p> <p>14 area of expertise.</p> <p>15 BY MR. JACKSON:</p> <p>16 Q. Dr. Priddy, as the founder and CEO of</p> <p>17 Plastic Expert Group, what do you do professionally?</p> <p>18 A. Consult, serve as an expert witness.</p> <p>19 Companies are constantly sending me plastic parts</p> <p>20 that have failed and ask me to figure out the root</p> <p>21 cause of the failure and make recommendations to</p> <p>22 them once I determine the cause why they are</p> <p>23 failing, how to fix it, how to remediate, how to</p> <p>24 redesign the part, change the material, do what</p>	<p>1 Q. Is the work you have done for medical</p> <p>2 device companies any different than the work you</p> <p>3 have done in this case?</p> <p>4 A. I have run OIT testing for medical device</p> <p>5 companies to, for example -- can I give an example?</p> <p>6 Q. Sure.</p> <p>7 A. Spectranetics was having a problem with</p> <p>8 degradation of one of their tubing materials that</p> <p>9 was failing, medical tubing. So they had me do a</p> <p>10 failure analysis and I determined that the tubing</p> <p>11 had degraded.</p> <p>12 And so I ran OIT testing to determine if</p> <p>13 it was an oxidation issue, for example. So to</p> <p>14 answer your question, it's a little bit different,</p> <p>15 but I'm using the same kinds of tests, yes.</p> <p>16 Q. You have run OIT tests for medical device</p> <p>17 companies?</p> <p>18 A. Yes.</p> <p>19 Q. You did an OIT test in this case?</p> <p>20 A. Yes.</p> <p>21 Q. Is there anything special or unique about</p> <p>22 the antioxidants used in the Prolene mesh?</p> <p>23 A. No, they are just basic workhorse</p> <p>24 antioxidants.</p>

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<p>1 Q. You have published peer-reviewed</p> <p>2 literature discussing antioxidants in plastics?</p> <p>3 MR. HUTCHINSON: Object to form.</p> <p>4 A. Yes, I have.</p> <p>5 BY MR. JACKSON:</p> <p>6 Q. Have you done work with antioxidants as</p> <p>7 part of your day job in your profession?</p> <p>8 A. Yes.</p> <p>9 Q. Your opinions in this case are based on</p> <p>10 your professional expertise as well as the documents</p> <p>11 you have reviewed in the peer-reviewed literature?</p> <p>12 MR. HUTCHINSON: Object to form.</p> <p>13 A. That's correct.</p> <p>14 BY MR. JACKSON:</p> <p>15 Q. The plaintiffs in this case asked you to</p> <p>16 opine on the chemical stability of Prolene; is that</p> <p>17 right?</p> <p>18 MR. HUTCHINSON: Form.</p> <p>19 A. Yes.</p> <p>20 BY MR. JACKSON:</p> <p>21 Q. If Ethicon had reached out to you 15 or</p> <p>22 20 years ago and asked you to do the same thing, if</p> <p>23 they had asked you to offer the same -- strike that.</p> <p>24 If Ethicon had reached out to you 15 or</p>	<p>1 A. No.</p> <p>2 Q. So why are you here to offer an opinion on</p> <p>3 a medical device?</p> <p>4 A. Because the medical device is plastic and</p> <p>5 I'm a plastics expert.</p> <p>6 Q. Dr. Priddy, you were asked a lot of</p> <p>7 questions earlier today about both DLTD and</p> <p>8 Santonox R. Do you remember that?</p> <p>9 A. Yes.</p> <p>10 Q. Does the presence of either of those</p> <p>11 antioxidants in the Prolene mesh alter your opinions</p> <p>12 in this case?</p> <p>13 A. No.</p> <p>14 MR. HUTCHINSON: Are you done?</p> <p>15 MR. JACKSON: I have no more</p> <p>16 questions.</p> <p>17 MR. HUTCHINSON: I got a couple of</p> <p>18 follow-up questions.</p> <p>19 EXAMINATION (Continued)</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Doctor, you testified that you were</p> <p>22 deposed in the AMS litigation as a fact witness?</p> <p>23 Did I understand that correctly?</p> <p>24 A. Yes.</p>
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<p>1 20 years ago and asked you to offer the same</p> <p>2 opinions for them, would you have done it?</p> <p>3 A. Yes.</p> <p>4 Q. Would you have run the same tests and</p> <p>5 analysis that you have run in this case?</p> <p>6 A. Most likely.</p> <p>7 Q. Is the testing and analysis that you have</p> <p>8 done in this case widely accepted in your industry?</p> <p>9 A. Yes.</p> <p>10 Q. As someone who has worked for medical</p> <p>11 device companies, is accelerated aging testing alone</p> <p>12 sufficient to determine the suitability of a</p> <p>13 material?</p> <p>14 A. No.</p> <p>15 Q. Why not?</p> <p>16 A. Because it is only an approximation. It</p> <p>17 just lets you know if there is a red flag there that</p> <p>18 needs to be followed up on or not.</p> <p>19 Q. Why did you review Ethicon documents in</p> <p>20 this case?</p> <p>21 A. I wanted to see the kind of testing that</p> <p>22 they performed and the data they generated on their</p> <p>23 Prolene mesh products.</p> <p>24 Q. You are not a medical doctor?</p>	<p>1 Q. What did you witness?</p> <p>2 A. I didn't write a report. I had done work</p> <p>3 as a consultant for AMS and so I was deposed, I</p> <p>4 guess, to just talk, as I recall, just talk about</p> <p>5 polypropylene oxidation and stability.</p> <p>6 Q. Was it a patent type litigation or was it</p> <p>7 a personal injury type of litigation?</p> <p>8 A. I think it was a class action litigation</p> <p>9 against AMS for their meshes, as I recall.</p> <p>10 Q. What was the substance of your testimony</p> <p>11 in the AMS litigation?</p> <p>12 MR. JACKSON: Objection, form.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. Just in general.</p> <p>15 A. It was generally similar to this, the</p> <p>16 oxidative stability of polypropylene. It was</p> <p>17 focused pretty much on chemistry of oxidation of</p> <p>18 polypropylene.</p> <p>19 Q. But you were not designated as an expert</p> <p>20 in that litigation; is that correct?</p> <p>21 A. That's correct.</p> <p>22 Q. Did you have a lawyer representing you?</p> <p>23 A. Representing me, I had one that hired me.</p> <p>24 Q. What did that lawyer hire you to do?</p>

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1 CERTIFICATE

2 GEORGIA:

3 HENRY COUNTY:

4 I hereby certify that the foregoing
5 deposition was reported, as stated in the
6 caption, and the questions and answers
7 thereto were reduced to the written page
8 under my direction; that the foregoing
9 pages 1 through 168 represent a true and
correct transcript of the evidence given.
I further certify that I am not in any
way financially interested in the result
of said case.

10 Pursuant to Rules and Regulations of
the Board of Court Reporting of the
11 Judicial Council of Georgia, I make the
following disclosure:

12 I am a Georgia Certified Court
Reporter. I am here as an independent
contractor for Golkow Global Litigation
13 Services.

14 I was contacted by the offices of
Golkow Global Litigation Services to
provide court reporting services for this
15 deposition. I will not be taking this
deposition under any contract that is
16 prohibited by O.C.G.A. 15-14-37 (a) or
(b).

17 I have no written contract to provide
reporting services with any party to the
18 case, any counsel in the case, or any
reporter or reporting agency from whom a
19 referral might have been made to cover
this deposition. I will charge my usual
20 and customary rates to all parties in the
case.

21 This, the 9th day of March, 2016.

22
23 MAXYNE BURSKY, CCR-2547
24

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EXHIBIT I

Scott A. Guelcher, Ph.D.

SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF KERN
CASE NO. S-1500-CV 279123 LHB

COLEEN M. PERRY,

PLAINTIFF

vs.

HUNG T. LUU, M.D.,
JOHNSON & JOHNSON, a New Jersey
Corporation; ETHICON, INC., a
New Jersey Corporation; and
DOES 1-60,

DEFENDANTS

The deposition of SCOTT A. GUELCHER, Ph.D.,
called by the Defendants for examination, taken
before Michelle E. Kerr, RPR, a Notary Public in and
for the Commonwealth of Kentucky, Daviess County, at
1719 West End Avenue, Nashville, Tennessee, on
December 18, 2014, commencing at 9:40 a.m.

Scott A. Guelcher, Ph.D.

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<p>1 INDEX</p> <p>2 PAGE</p> <p>3 Direct Examination by Mr. Snell 4</p> <p>4 Cross-Examination by Mr. Rosen 265</p> <p>5 Cross-Examination by Mr. Kuntz 265</p> <p>6 Redirect Examination by Mr. Snell 267</p> <p>7</p> <p>8</p> <p>9</p> <p>10 EXHIBITS</p> <p>11 PAGE</p> <p>12 1 - Article by Clave 49</p> <p>13 2 - Pathology Slides - Coleen Perry 90</p> <p>14 (Three Sets)</p> <p>15 3 - Thumb Drive Containing Reliance 150</p> <p>16 Documents</p> <p>17 4 - Summary of Opinions by Dr. Guelcher 192</p> <p>18</p> <p>19 5 - Document Containing Listing of 241</p> <p>20 Cases</p> <p>21 6 - Curriculum Vitae 242</p> <p>22 7 - Printout from Vanderbilt University 257</p> <p>23 Medical Center Website</p> <p>24</p> <p>25</p>	<p>1 A By plaintiff's counsel, Jeff Kuntz and Tom</p> <p>2 Cartmell.</p> <p>3 Q And what did you understand your assignment</p> <p>4 to be in relation to the Coleen Perry case?</p> <p>5 A Assignment, I'm not sure what you mean by</p> <p>6 that.</p> <p>7 Q What did you understand your purpose was to</p> <p>8 be as an expert involved in the Perry case?</p> <p>9 A Well, I was testifying about defects in the</p> <p>10 Abbrevio mesh.</p> <p>11 Q Did you say effects?</p> <p>12 A Defects in the Abbrevio mesh product.</p> <p>13 Q You have given other deposition and trial</p> <p>14 testimony in mesh litigation, correct?</p> <p>15 A Yes, I have.</p> <p>16 Q You testified in the Huskey case that</p> <p>17 involved Ethicon's TVT-O product, correct?</p> <p>18 A I did.</p> <p>19 Q You were deposed and gave trial in West</p> <p>20 Virginia, correct?</p> <p>21 A That's correct.</p> <p>22 Q And at the time that you gave that testimony,</p> <p>23 it was under oath as well, correct?</p> <p>24 A That's correct.</p> <p>25 Q And did you tell the truth in that testimony?</p>

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<p>1 A Yes.</p> <p>2 Q How many hours have you spent on the Perry</p> <p>3 case?</p> <p>4 A I'm not sure. I haven't billed any invoices</p> <p>5 for time yet, so I don't know the total</p> <p>6 number of hours.</p> <p>7 Q Can you give me your best estimate?</p> <p>8 A I don't know. Maybe 20. But when I submit</p> <p>9 my invoices, that will be the more reliable</p> <p>10 number. I haven't added it up yet.</p> <p>11 Q Well, do you have the invoices on your</p> <p>12 calendar?</p> <p>13 A No.</p> <p>14 Q In the Huskey case, you testified that you</p> <p>15 submitted your invoices to Dr. Dunn in</p> <p>16 connection with that matter. Do you recall</p> <p>17 giving that testimony?</p> <p>18 A That's correct.</p> <p>19 Q Are you submitting your invoices to Dr. Dunn</p> <p>20 in the Perry case?</p> <p>21 A I'm not sure yet how that will be. I'll be</p> <p>22 billing -- my plan is -- it's not resolved</p> <p>23 yet, whether I will independently or through</p> <p>24 Dr. Dunn's company.</p> <p>25 Q How do you track your time that you spend in</p>	<p>1 Huskey case. Do you recall giving that</p> <p>2 testimony?</p> <p>3 MR. KUNTZ: Objection.</p> <p>4 A I'm not sure what you mean by a cut.</p> <p>5 BY MR. SNELL:</p> <p>6 Q In the Huskey case, as I recall it, you</p> <p>7 received \$200 per hour for review and work,</p> <p>8 correct?</p> <p>9 A I don't believe that's -- well, it was 200 or</p> <p>10 210. He raised the rates. Okay. It was 200</p> <p>11 or 210. The rates have been changed, and I</p> <p>12 don't remember if it was before or after</p> <p>13 Huskey. It may have been 200. It may have</p> <p>14 been 210. I can't remember.</p> <p>15 Q And Dr. Dunn billed \$275 an hour for your</p> <p>16 review time, correct?</p> <p>17 A If I bill 200, then Dr. Dunn would have</p> <p>18 billed 275.</p> <p>19 Q And is it your testimony that that</p> <p>20 arrangement has changed within the last one</p> <p>21 to two months?</p> <p>22 A Yes. I have not submitted any invoices for</p> <p>23 this case, but the plan for moving forward is</p> <p>24 for me to submit invoices independent of</p> <p>25 Dr. Dunn's company.</p>
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<p>1 the Perry case?</p> <p>2 A I have some paper records, but it's not --</p> <p>3 nothing is official. I've not been</p> <p>4 releasing -- in the past, all the invoices</p> <p>5 have been submitted through Dr. Dunn's</p> <p>6 company. Nothing is official until I submit</p> <p>7 the invoices. I don't have the invoices</p> <p>8 right now.</p> <p>9 Q Well, in the Huskey case, you testified under</p> <p>10 oath that you submitted monthly invoices to</p> <p>11 Dr. Dunn, which included the time spent, the</p> <p>12 time of day spent and a brief description of</p> <p>13 your activities. Do you recall giving that</p> <p>14 testimony?</p> <p>15 A I do.</p> <p>16 Q And at what point in time has that changed?</p> <p>17 A Very recently. In the past maybe month or</p> <p>18 two.</p> <p>19 Q When was the last time you sent an invoice to</p> <p>20 Dr. Dunn with regard to your work as an</p> <p>21 expert in mesh litigation?</p> <p>22 A I don't remember. Maybe a month or two ago.</p> <p>23 I don't remember the date.</p> <p>24 Q As I understand it, Dr. Dunn received a cut</p> <p>25 from the amount billed for your work in the</p>	<p>1 Q Do you have your own company that you will be</p> <p>2 submitting invoices under?</p> <p>3 A I do.</p> <p>4 Q What's the name of that company?</p> <p>5 A Guelcher Consulting, LLC.</p> <p>6 Q In the Huskey matter, you testified that you</p> <p>7 kept a calendar and a recording of your time</p> <p>8 spent and the days that you worked as an</p> <p>9 expert. Do you recall giving that testimony?</p> <p>10 A I do.</p> <p>11 Q Have you done the same thing here?</p> <p>12 A I have not. Not in the same way.</p> <p>13 Q Why not?</p> <p>14 A I just changed it. I have a right to change</p> <p>15 the way I keep the time.</p> <p>16 Q So what materials or documents do you have</p> <p>17 that would reflect the time you've spent up</p> <p>18 until the time of this deposition for the</p> <p>19 Perry case?</p> <p>20 A I don't have them yet because I haven't</p> <p>21 submitted the invoices. That's what I said.</p> <p>22 Q I'm not asking about invoices.</p> <p>23 I'm asking what other materials or</p> <p>24 documents -- what would you look to to draft</p> <p>25 an invoice so that you would know the</p>

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<p>1 accurate amount of hours for your billing 2 that you would submit? 3 A I have some paper at home. 4 Q What paper at home? 5 A Well, I have a piece of paper that has hours 6 written on it, but I haven't added everything 7 up yet because I haven't submitted the 8 invoice. 9 Q Is this a piece of paper in a notebook or -- 10 A No, it's just a note. 11 Q Do you have a copy of that that you can give 12 to counsel? 13 A No, I don't, because we haven't been doing 14 that. We've been providing invoices, and 15 Dr. Dunn was providing invoices, and I just 16 don't have an invoice yet that I've sent in. 17 Until it's finalized, I don't -- I've not 18 been submitting records of time until there 19 is a final invoice. 20 MR. SNELL: Well, I'm going to 21 make a request that you get a copy of that to 22 counsel, and we'll attach it to the 23 deposition. 24 MR. KUNTZ: We'll get you a 25 copy.</p>	<p>1 Q For over a year, you submitted invoices 2 through Dr. Dunn and his company, correct? 3 A That's correct. 4 Q Is it your testimony that there was nothing 5 that made you decide to go out and become 6 independent of Dr. Dunn? 7 A Well, that's not what you asked me the first 8 time. You ask me what happened, implying 9 that something disruptive happened in our 10 working relationship, which nothing happened. 11 It's just a decision to do this 12 independently. 13 Q How much are you billing now for your work -- 14 A The same rate. 15 Q Let me finish my question. 16 A Sure. 17 Q How much are you billing for your time as an 18 expert in the Perry case for review of 19 materials? 20 A The same rates as Dr. Dunn. 21 Q Can you tell me how much per hour? 22 A Dr. Dunn raised his rates from 275 to 285 for 23 report writing, reviewing of documents, etc. 24 I will be charging that rate. For testimony, 25 I just can't remember the number right now.</p>
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<p>1 A I can send an invoice after today and that 2 will make it official. Is that okay? 3 BY MR. SNELL: 4 Q Well, that's fine. But I'd like to know what 5 it is because I will have questions about 6 that potentially. 7 A What is? I don't understand. You said you'd 8 like to know what it is if I send you an 9 invoice. You know what it is. It's an 10 invoice that says my hours and what I did, so 11 I'm not sure what you're looking for. 12 Q Well, right now you currently have -- you 13 testified you have a document that has your 14 hours and the time you spent. That's the 15 document I would like. If you draft an 16 invoice, I would like that as well. 17 A Okay. 18 Q When did you form Guelcher Consulting, LLC? 19 A It's been very recent. In the past few weeks 20 maybe. 21 Q What happened between you and Dr. Dunn that 22 led you to believe that you should go out 23 independent of Dr. Dunn? 24 A Nothing happened with Dr. Dunn. I'm not sure 25 what you're asking me.</p>	<p>1 I think it's maybe 385 is a number for 2 testimony, but that would be on the invoice. 3 I can't remember the number right now. 4 Q So it's your intention to bill \$285 per hour 5 for reviewing materials and report writing 6 and things like that? 7 A That's what Dr. Dunn was billing. And since 8 I'm doing the same activities, I thought it 9 reasonable to bill the same rate. 10 Q Dr. Dunn is not an expert in this case. 11 You're aware of that, correct? 12 A My understanding is that Dr. Dunn has not 13 been produced as an expert witness for 14 Plaintiffs. 15 Q All right. So for you -- I just want to get 16 a clean answer without injecting Dr. Dunn 17 into this Q and A. The rates that you, 18 Dr. Guelcher, are charging for report writing 19 and review of documents for this matter in 20 the Perry case will be \$285 per hour; is that 21 correct? 22 A That's correct. 23 Q The rate that you will charge for testimony, 24 as best as you can figure at this point in 25 time, is \$385 per hour?</p>

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<p>1 A That's correct.</p> <p>2 Q Will you have a different rate for trial</p> <p>3 testimony if you are called to testify at</p> <p>4 trial?</p> <p>5 A I don't believe so. I intend to use the same</p> <p>6 rates that were being billed in the past, and</p> <p>7 there was no difference between trial and</p> <p>8 deposition testimony. Those numbers were the</p> <p>9 same. So whatever those numbers are, it will</p> <p>10 be the same. There won't be a difference.</p> <p>11 Q You understand that this trial will be in</p> <p>12 California?</p> <p>13 A Yes.</p> <p>14 Q And you're agreeable to traveling to</p> <p>15 California for trial?</p> <p>16 A Yes.</p> <p>17 Q Your expenses of traveling to California,</p> <p>18 would you bill for those?</p> <p>19 A That's what Dr. Dunn has done in the past,</p> <p>20 and I would continue that practice.</p> <p>21 Q So if you come to trial in California, you</p> <p>22 will bill for your expenses, such as air</p> <p>23 fare, and hotel room, and meals, correct?</p> <p>24 A Yes, that's correct.</p> <p>25 Q Have you ever met Mrs. Perry?</p>	<p>1 have you ever spoken to him?</p> <p>2 A No.</p> <p>3 Q Okay. Dr. Donald Marks, he is another</p> <p>4 expert --</p> <p>5 A I have not.</p> <p>6 Q You have not spoken with him?</p> <p>7 A No.</p> <p>8 Q Have you reviewed any expert reports or</p> <p>9 expert declarations in the Perry case?</p> <p>10 A Yes.</p> <p>11 MR. KUNTZ: Aside from this own?</p> <p>12 MR. SNELL: Yes, of course.</p> <p>13 BY MR. SNELL:</p> <p>14 Q Let me just take that off the table and</p> <p>15 reformulate.</p> <p>16 Setting aside your expert declaration</p> <p>17 listed opinions, have you reviewed any other</p> <p>18 experts' declarations or listed opinions?</p> <p>19 A Declarations, no, I don't believe so.</p> <p>20 Q Okay. For your opinions in this case, you're</p> <p>21 not relying on the declarations or reports of</p> <p>22 any other experts, correct?</p> <p>23 A No, I'm not relying on any other</p> <p>24 declarations.</p> <p>25 Q You're not relying on any other experts'</p>
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<p>1 A I have not.</p> <p>2 Q Have you spoken to Mrs. Perry?</p> <p>3 A I have not.</p> <p>4 Q Have you ever spoken to any of Mrs. Perry's</p> <p>5 family or friends?</p> <p>6 A No.</p> <p>7 Q Have you ever spoken with any of Mrs. Perry's</p> <p>8 doctors?</p> <p>9 A No.</p> <p>10 Q Okay. Have you spoken with any other experts</p> <p>11 about the Perry case?</p> <p>12 A Any other experts defined as --</p> <p>13 Q Defined as -- let me ask you this. Besides</p> <p>14 yourself, who do you understand to be the</p> <p>15 other experts besides yourself in the Perry</p> <p>16 case?</p> <p>17 A I don't know who the other experts are that</p> <p>18 they are calling. I haven't spoken with</p> <p>19 them.</p> <p>20 Q So you have not spoken with a Dr. Rosenzweig</p> <p>21 about the Perry case?</p> <p>22 A I have not.</p> <p>23 Q Have you ever spoken with Dr. Rosenzweig?</p> <p>24 A I have not.</p> <p>25 Q Dr. Michael Thomas Margolis from California,</p>	<p>1 opinions, correct?</p> <p>2 A Yes.</p> <p>3 Q Do you know if any independent medical</p> <p>4 examinations have been done on Mrs. Perry?</p> <p>5 A I'm not aware of any of those outcomes of</p> <p>6 those medical examinations. I've not</p> <p>7 reviewed that.</p> <p>8 Q So you haven't reviewed any of the IME</p> <p>9 outcomes or reports in this Perry case,</p> <p>10 correct?</p> <p>11 A No.</p> <p>12 Q I'm not correct?</p> <p>13 A I have not reviewed, yeah. I'm sorry.</p> <p>14 Q Okay. And you're not relying on the outcomes</p> <p>15 of any IME reports; is that correct?</p> <p>16 A Yes, that's correct.</p> <p>17 Q When you do issue your invoices or invoice</p> <p>18 for the Perry case, will the check be made</p> <p>19 payable to Guelcher Consulting, LLC, or to</p> <p>20 you personally?</p> <p>21 A It will be made to the LLC. I'm the sole</p> <p>22 owner of the LLC, so it will be made to the</p> <p>23 LLC.</p> <p>24 Q Is Guelcher Consulting, LLC, a Tennessee</p> <p>25 corporation?</p>

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<p>1 A Yes. It's been registered with the secretary</p> <p>2 of state.</p> <p>3 Q As I understand it from your testimony at</p> <p>4 Huskey and other matters, you believe your</p> <p>5 expertise is in the field of biomaterials</p> <p>6 design?</p> <p>7 A That's one way of saying it. I have</p> <p>8 expertise in biomaterials science and</p> <p>9 engineering. Another way you could say it is</p> <p>10 that my work involves design of materials for</p> <p>11 use as bone grafts or skin grafts, design of</p> <p>12 biomaterials as diagnostics for studying</p> <p>13 cancer metastasis.</p> <p>14 Q You have a Ph.D., correct?</p> <p>15 A Yes.</p> <p>16 Q Any higher education than that?</p> <p>17 A I did a postdoctoral research training at</p> <p>18 Carnegie Mellon in biomedical engineering.</p> <p>19 Q But that was not something for which a degree</p> <p>20 was earned; is that correct?</p> <p>21 A It's not a degree, but it's postdoctoral</p> <p>22 training. It counts as training.</p> <p>23 Q You're not a medical doctor, correct?</p> <p>24 A No, I'm not a medical doctor.</p> <p>25 Q You're not a pathologist?</p>	<p>1 course on polymer science and engineering at</p> <p>2 Vanderbilt.</p> <p>3 Q In prior cases, as I understand it, and have</p> <p>4 read your testimony, Dr. Dunn, if testing was</p> <p>5 done, he would have been the one to perform</p> <p>6 the testing on meshes?</p> <p>7 A That's correct, Dr. Dunn did the testing.</p> <p>8 Q Is there a certain reason for that?</p> <p>9 A The reason relates to the nature of our</p> <p>10 employments at Vanderbilt. Dr. Dunn is a</p> <p>11 professor of the practice. I'm a tenured</p> <p>12 associate professor with a federally-funded</p> <p>13 research program. And so we have different</p> <p>14 appointments, that's the reason.</p> <p>15 Q I don't understand that.</p> <p>16 Can only professors do the type of</p> <p>17 testing that he performed in the prior cases?</p> <p>18 A I'm qualified to do the testing. It's that I</p> <p>19 have graduate students working in my</p> <p>20 laboratory on federal research grants.</p> <p>21 Dr. Dunn has a company with employees. It's</p> <p>22 simpler for him to do the testing than for me</p> <p>23 from an administrative perspective. So that</p> <p>24 doesn't have anything to do with</p> <p>25 qualifications or ability. It's more because</p>
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<p>1 A I'm not a pathologist.</p> <p>2 Q You don't treat any patients, correct?</p> <p>3 A I don't treat patients.</p> <p>4 Q You're not a toxicologist, correct?</p> <p>5 A I'm not a toxicologist.</p> <p>6 Q What is the difference between your expertise</p> <p>7 and Dr. Dunn's expertise?</p> <p>8 A So Dr. Dunn and I have overlapping expertise</p> <p>9 in polymer science and engineering. My</p> <p>10 expertise is differentiated from Dr. Dunn's</p> <p>11 in biomaterials, preclinical testing of</p> <p>12 biomaterials, evaluation of biomaterials</p> <p>13 using in vitro and in vivo models. Those</p> <p>14 would be some examples of how my expertise is</p> <p>15 differentiated from Dr. Dunn's.</p> <p>16 Q Is Dr. Dunn more of a polymer chemist than</p> <p>17 you are?</p> <p>18 A I would not state it this way. I've had</p> <p>19 extensive experience in polymer chemistry,</p> <p>20 science and engineering. I've worked for</p> <p>21 several companies in the area of polymers.</p> <p>22 My postdoctoral training was in polymers for</p> <p>23 bone scaffolds. And for the past ten years</p> <p>24 at Vanderbilt, I've been working on polymers</p> <p>25 and I taught -- and I developed and taught a</p>	<p>1 of these practical reasons.</p> <p>2 Q So you have graduate students working under</p> <p>3 you who are being subsidized, whose work is</p> <p>4 being subsidized by federal funding; is that</p> <p>5 correct?</p> <p>6 A I wouldn't say it's being subsidized. The</p> <p>7 work is being funded by federal funding, and</p> <p>8 in some cases, by corporate funding. Their</p> <p>9 stipends are paid either from fellowships or</p> <p>10 from the grants, not from the consulting.</p> <p>11 Q Okay. Well, what about the fact of graduate</p> <p>12 students working under you who are supported</p> <p>13 by federal funding, what affect does that</p> <p>14 have on why Dr. Dunn did the testing and you</p> <p>15 didn't?</p> <p>16 A Well, to have graduate students working on</p> <p>17 that sort of testing would require a</p> <p>18 disclosure to the university, so I haven't</p> <p>19 had them involved. I've disclosed the</p> <p>20 consulting activity to the university</p> <p>21 required by the policy, but to have graduate</p> <p>22 students involved would require more, and I</p> <p>23 just haven't done that at this time.</p> <p>24 Q What type of disclosure did you make to the</p> <p>25 university with regard to your goal as an</p>

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<p>1 expert witness?</p> <p>2 A Every year we are required to file a</p> <p>3 disclosure report that would include --</p> <p>4 because I have NIH grants, the NIH requires</p> <p>5 us to disclose travel funded by third</p> <p>6 parties. I'm required to disclose</p> <p>7 relationships with companies that I have had</p> <p>8 grants from companies in the past, consulting</p> <p>9 relationships with companies. These</p> <p>10 activities are disclosed.</p> <p>11 In the past what I've disclosed is that I</p> <p>12 was a consultant working for Polymer and</p> <p>13 Chemical Technologies.</p> <p>14 Q So your disclosure stated that you worked as</p> <p>15 a consultant in polymer and --</p> <p>16 A For Polymer and Chemical Technologies.</p> <p>17 That's Dr. Dunn's company. So last year's</p> <p>18 disclosure, that's what I have filed. I have</p> <p>19 to update it this year again.</p> <p>20 Q Did you identify in your disclosure that you</p> <p>21 were serving as an expert on behalf of</p> <p>22 plaintiffs in the transvaginal mesh</p> <p>23 litigation?</p> <p>24 A We're not required to disclose the activity,</p> <p>25 only the fact that we're consulting.</p>	<p>1 A That's a complex question. It depends on</p> <p>2 what's being used and the specific faculty</p> <p>3 member. It would have to be discussed with</p> <p>4 the university. I don't know the answer to</p> <p>5 that. There is not a fixed answer to that</p> <p>6 question.</p> <p>7 Q If you have one of your graduate students who</p> <p>8 is supported by federal funding analyze</p> <p>9 meshes from the mesh litigation, would you</p> <p>10 have to disclose that to anyone?</p> <p>11 A I would discuss that with the dean's office.</p> <p>12 But Dr. Dunn's company did the testing, so --</p> <p>13 Q Where is Dr. Dunn's company located at?</p> <p>14 A At his residence in Nashville.</p> <p>15 Q He has employees working out of his home in</p> <p>16 Nashville?</p> <p>17 A I can't speak to those details about</p> <p>18 Dr. Dunn's company. I don't know how he</p> <p>19 operates his company other than his business</p> <p>20 relationship with me.</p> <p>21 Q Do you know if Dr. Dunn utilized any of the</p> <p>22 graduate students at Vanderbilt in any</p> <p>23 analyses pertaining to transvaginal mesh?</p> <p>24 A Not to my knowledge.</p> <p>25 Q Do you know if Dr. Dunn utilized any</p>
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<p>1 Q So you did not disclose that you were</p> <p>2 consulting with plaintiffs' attorneys in</p> <p>3 transvaginal mesh litigation?</p> <p>4 A I don't remember what I disclosed right now,</p> <p>5 the exact details. I disclosed that I had a</p> <p>6 consulting relationship. I don't remember</p> <p>7 the detail of what I exactly disclosed. I</p> <p>8 would have to look at it again.</p> <p>9 Q Now, that you're billing your services</p> <p>10 directly through your own corporation, are</p> <p>11 you going to disclose that you are consulting</p> <p>12 and serving as an expert to plaintiffs in</p> <p>13 transvaginal mesh litigation?</p> <p>14 A When I submit the invoices, I will update the</p> <p>15 disclosure, but that hasn't been finalized</p> <p>16 yet. When I submit the invoices, I will</p> <p>17 update the disclosure.</p> <p>18 Q Where does this disclosure get submitted to</p> <p>19 within Vanderbilt?</p> <p>20 A At the dean's office, dean of engineering.</p> <p>21 Q If you do any testing of meshes in your role</p> <p>22 as a plaintiff's expert, and you utilize any</p> <p>23 of Vanderbilt's equipment, personnel, or any</p> <p>24 other assets owned by Vanderbilt, do you have</p> <p>25 to give prior notice of that to Vanderbilt?</p>	<p>1 Vanderbilt personnel besides yourself in any</p> <p>2 analyses or investigation pertaining to</p> <p>3 transvaginal mesh?</p> <p>4 A Again, Dr. Dunn would have to speak to that.</p> <p>5 I don't know.</p> <p>6 Q Who is your immediate supervisor currently?</p> <p>7 A My department chair, Kane Jennings.</p> <p>8 Q Could you spell that?</p> <p>9 A K-A-N-E Jennings.</p> <p>10 Q And that's within the department of what?</p> <p>11 A Chemical and biomolecular engineering.</p> <p>12 Q So you work within the Department of Chemical</p> <p>13 and Biomolecular Engineering at Vanderbilt?</p> <p>14 A That is correct.</p> <p>15 Q Is that a particular school at Vanderbilt?</p> <p>16 A That department is within the school of</p> <p>17 engineering.</p> <p>18 Q Besides Dr. Dunn, who, if anyone else at</p> <p>19 Vanderbilt is aware that you are serving as</p> <p>20 an expert for plaintiffs in the transvaginal</p> <p>21 mesh litigation?</p> <p>22 A Professor Ken Debelak, D-E-B-E-L-A-K. He's</p> <p>23 an Associate Professor of Chemical and</p> <p>24 Biomolecular Engineering at Vanderbilt.</p> <p>25 Dr. Dunn retained him through his company as</p>

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<p>1 an expert in prior litigation over a year</p> <p>2 ago. I believe Dr. Debelak was deposed in</p> <p>3 this first case, but not since.</p> <p>4 Q Have you had anyone at Vanderbilt perform any</p> <p>5 activity on your behalf with regard to</p> <p>6 anything you've done in the transvaginal mesh</p> <p>7 litigation as an expert?</p> <p>8 A So I have a graduate student who was doing</p> <p>9 oxidative degradation testing through her</p> <p>10 dissertation project, and she provided --</p> <p>11 well, I asked my graduate students to write</p> <p>12 standard operating procedures for everything</p> <p>13 we do. I review and discuss those procedures</p> <p>14 with them and approve them, and she gave that</p> <p>15 protocol to Professor Dunn.</p> <p>16 Q What's the name of this graduate student?</p> <p>17 A Anne Talley, T-A-L-L-E-Y.</p> <p>18 Q Let me see if I understand this. So you</p> <p>19 asked all of your graduate students to write</p> <p>20 SOP's?</p> <p>21 A So for anything that we do in the laboratory,</p> <p>22 for any polymer that we make, for any</p> <p>23 analysis that we run, such as oxidative</p> <p>24 degradation testing, we review the literature</p> <p>25 and prepare a standard operating procedure or</p>	<p>1 solution of 20 percent hydrogen peroxide with</p> <p>2 cobalt chloride, and I don't remember the</p> <p>3 exact amount. That's the solution.</p> <p>4 Q And this solution is used for the in vitro</p> <p>5 testing of mesh?</p> <p>6 A This solution was first developed by Dr. Jim</p> <p>7 Anderson in 1993. It was first published --</p> <p>8 his group published a number of papers on it.</p> <p>9 I published two papers with it. It's used to</p> <p>10 assess the degradation of biomaterials under</p> <p>11 oxidative conditions that are similar to</p> <p>12 those in the human body, more specifically,</p> <p>13 that are similar to those under conditions</p> <p>14 where there are adherent inflammatory cells</p> <p>15 in the biomaterial, the foreign body</p> <p>16 reaction, I should say, the effects of the</p> <p>17 foreign body reaction on the stability of the</p> <p>18 biomaterial.</p> <p>19 It's a very general well-known</p> <p>20 established test that's been cited dozens of</p> <p>21 times.</p> <p>22 Q So did Ms. Talley or any of your other</p> <p>23 graduate students do any in vitro testing on</p> <p>24 the mesh?</p> <p>25 A No. As I said before, that testing was done</p>
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<p>1 an SOP for the procedure, and I believe</p> <p>2 that's part of student training. These are</p> <p>3 the types of activities they will do in the</p> <p>4 industry, so I ask my students to write these</p> <p>5 types of documents.</p> <p>6 Q What did you ask Anne Talley to do</p> <p>7 specifically that pertained to your work as</p> <p>8 an expert in the transvaginal mesh</p> <p>9 litigation?</p> <p>10 A I didn't ask her -- I asked her to write the</p> <p>11 SOP for the medium, preparing the medium.</p> <p>12 And then Dr. Dunn asked her for that SOP is</p> <p>13 my understanding.</p> <p>14 Q Why did you ask Ms. Talley to write the SOP</p> <p>15 for the preparation of the medium?</p> <p>16 A Well, she was the one that was working in</p> <p>17 this area on her research project, so she had</p> <p>18 the most knowledge about it.</p> <p>19 Q When you say medium, what medium are you</p> <p>20 referencing?</p> <p>21 A The medium that was used in the in vitro</p> <p>22 testing with the mesh.</p> <p>23 Q What was that medium?</p> <p>24 A It's a solution of 20 percent cobalt chloride</p> <p>25 -- I'm sorry. Strike that. It was a</p>	<p>1 by Dr. Dunn's company.</p> <p>2 Q Was the testing done by Dr. Dunn's company</p> <p>3 before or after Ms. Talley's SOP was given to</p> <p>4 Dr. Dunn?</p> <p>5 A I believe it was after, because they used</p> <p>6 that SOP to prepare the solution. These</p> <p>7 activities were done by Dr. Dunn, but I don't</p> <p>8 know who in his company did what. I just</p> <p>9 know that my lab through Anne provided them</p> <p>10 with a solution with a -- strike that -- with</p> <p>11 an SOP for preparing the solution, and then</p> <p>12 they did the testing.</p> <p>13 Q Did Ms. Talley know that she was writing an</p> <p>14 SOP that would be given to plaintiffs'</p> <p>15 experts in the transvaginal mesh litigation</p> <p>16 for utilization in certain testing?</p> <p>17 A She did not prepare the SOP for plaintiffs.</p> <p>18 She prepared the SOP for use in my</p> <p>19 laboratory. She was aware of the mesh</p> <p>20 litigation, but she was not -- she did not</p> <p>21 write it for this. It's an SOP for my</p> <p>22 laboratory. It falls within the scope of her</p> <p>23 activities on her funded research project.</p> <p>24 MR. SNELL: Move to strike.</p> <p>25 BY MR. SNELL:</p>

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<p>1 Q Did Ms. Talley know that she was preparing an</p> <p>2 SOP that would be given to a plaintiff's</p> <p>3 expert for use in transvaginal mesh</p> <p>4 litigation?</p> <p>5 A The way you asked that question, no, I don't</p> <p>6 believe so. It was written for my</p> <p>7 laboratory. She did not write it for the</p> <p>8 testing. It's an SOP that was in my</p> <p>9 laboratory.</p> <p>10 Q How long did it take Ms. Talley to write this</p> <p>11 SOP?</p> <p>12 A I don't know.</p> <p>13 Q Did you assign Ms. Talley to write this</p> <p>14 particular SOP regarding this testing?</p> <p>15 A I believe so. I asked her to write the SOP</p> <p>16 for the procedure in general to use in our</p> <p>17 lab. We use it for other projects as well.</p> <p>18 Q You were aware when you asked Ms. Talley to</p> <p>19 write the SOP regarding the testing, that it</p> <p>20 would be used by Dr. Dunn in his role as an</p> <p>21 expert for plaintiffs in the mesh litigation?</p> <p>22 A I was aware of that.</p> <p>23 Q Did Dr. Dunn give Ms. Talley any money or</p> <p>24 remuneration for writing this SOP that he</p> <p>25 used in his role as an expert in the mesh</p>	<p>1 this SOP?</p> <p>2 A I don't remember. I don't know when exactly</p> <p>3 she wrote it or when it was revised or</p> <p>4 finalized. I don't remember.</p> <p>5 Q Well, was it this year or last year?</p> <p>6 A I don't know.</p> <p>7 Q When did Dr. Dunn do this testing that he</p> <p>8 utilized Ms. Talley's SOP that she wrote</p> <p>9 while as a graduate student for you?</p> <p>10 A It was done in September.</p> <p>11 Q Of 2014?</p> <p>12 A Yeah.</p> <p>13 Q So, certainly, Ms. Talley would have been</p> <p>14 working on this SOP during the calendar year</p> <p>15 of 2014, correct?</p> <p>16 A She would have been working on it.</p> <p>17 Typically, these are documents that we write</p> <p>18 and we revise, so I have had students write</p> <p>19 SOP's, and then other students come back and</p> <p>20 revise them. That's how we do it. We revise</p> <p>21 them based on new papers that have been</p> <p>22 published, new information, so I don't know</p> <p>23 the history of the document. I can't</p> <p>24 remember that.</p> <p>25 Q Is Ms. Talley currently a graduate student at</p>
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<p>1 litigation?</p> <p>2 A He wouldn't give her remuneration because it</p> <p>3 was written within the course of her work at</p> <p>4 Vanderbilt and her project.</p> <p>5 Q So the answer is, no, he didn't give her any</p> <p>6 money?</p> <p>7 A No.</p> <p>8 Q And did you give Ms. Talley any money or</p> <p>9 remuneration for writing the SOP that you</p> <p>10 were aware of that would be used in testing</p> <p>11 meshes in transvaginal litigation?</p> <p>12 A I didn't give her money because it was</p> <p>13 written for her research project for her work</p> <p>14 at Vanderbilt.</p> <p>15 Q So the answer is no, you didn't give her any</p> <p>16 money, correct?</p> <p>17 A No, but for that reason. It wasn't written</p> <p>18 for the mesh litigation.</p> <p>19 Q Other than Ms. Anne Talley, have you involved</p> <p>20 any of your other graduate students in any</p> <p>21 testing or analyses pertaining to your work</p> <p>22 as an expert in the transvaginal mesh</p> <p>23 litigation?</p> <p>24 A No.</p> <p>25 Q How long ago was it that Ms. Talley wrote</p>	<p>1 Vanderbilt?</p> <p>2 A Yes.</p> <p>3 Q If you had done any of the types of testing</p> <p>4 that Dr. Dunn has performed in his role as an</p> <p>5 expert in the transvaginal mesh litigation on</p> <p>6 the mesh, what type of paperwork or</p> <p>7 disclosures would you have had to give to</p> <p>8 Vanderbilt?</p> <p>9 A I don't know. It's difficult to answer these</p> <p>10 questions. We tend to address them when --</p> <p>11 I just -- as I said earlier, I have not been</p> <p>12 doing testing of materials for litigation at</p> <p>13 Vanderbilt, so I don't know what I would have</p> <p>14 to do. So far I've disclosed the consulting</p> <p>15 activity. I may very well make additional</p> <p>16 disclosures as we move along and the</p> <p>17 situation changes, but it's a very fluid</p> <p>18 situation.</p> <p>19 We disclose these types of things as they</p> <p>20 arise. So it's difficult to say without</p> <p>21 actually seeing the situation.</p> <p>22 Q Does Vanderbilt require you to disclose any</p> <p>23 relationships upon which you receive outside</p> <p>24 monies?</p> <p>25 A I already answered this. We're required to</p>

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<p>1 disclose consulting relationships. When I</p> <p>2 submit a grant application, I'm required to</p> <p>3 disclose whether I have a significant</p> <p>4 financial interest. The NIH changed the</p> <p>5 rules in 2012. I disclose whether there is a</p> <p>6 significant financial interest, and then the</p> <p>7 dean's office works with me to figure out if</p> <p>8 there is a conflict, and if there is, how do</p> <p>9 we manage it.</p> <p>10 So there is no fixed set procedure. It's</p> <p>11 very much handled on a case-by-case basis.</p> <p>12 And disclosures are continuously updated as</p> <p>13 new information becomes available.</p> <p>14 Q How is significant financial interest</p> <p>15 defined?</p> <p>16 A The NIH defines a significant financial</p> <p>17 interest as \$5,000 a year. That's one way to</p> <p>18 define it. Another is equity. Strike that.</p> <p>19 The NIH defines it as \$5,000 or greater.</p> <p>20 Financial interest, that could be cash. That</p> <p>21 could be equity. That could be any form of</p> <p>22 compensation, but the threshold is \$5,000.</p> <p>23 Q Have all monies you receive in your role as</p> <p>24 an expert in the transvaginal mesh litigation</p> <p>25 for the calendar year 2014 been paid to you</p>	<p>1 independent role now as an expert and</p> <p>2 billing as an expert will have on your</p> <p>3 ability to work or run a lab that has</p> <p>4 federally-funded research?</p> <p>5 A Yes, I have.</p> <p>6 Q And what affect, if any, have you learned</p> <p>7 about that?</p> <p>8 A I'm contemplating updating my disclosure.</p> <p>9 And -- well, I will leave it at that.</p> <p>10 Q Have you had any discussions with anyone at</p> <p>11 Vanderbilt about ways you could work around</p> <p>12 the ramifications that the receipt of federal</p> <p>13 funding has on your role as an expert?</p> <p>14 MR. KUNTZ: Objection.</p> <p>15 A I don't like this word work around. That's</p> <p>16 not what we do. We identify conflicts. We</p> <p>17 disclose information to the dean's office.</p> <p>18 We work with the dean's office to identify</p> <p>19 conflicts. If conflicts are identified, we</p> <p>20 work with the dean's office and the general</p> <p>21 counsel's office to identify and manage a</p> <p>22 plan, which is then approved -- approved by</p> <p>23 the conflict of interest committee.</p> <p>24 I've been through this process multiple</p> <p>25 times. I've had management plans. I've been</p>
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<p>1 through Dr. Dunn's company?</p> <p>2 A The money I have received has all been</p> <p>3 received through Dr. Dunn's company, that's</p> <p>4 right, yes. The money I received, yes.</p> <p>5 Q Does anyone at Vanderbilt know the scope of</p> <p>6 Dr. Dunn's company?</p> <p>7 A I can't speak to Dr. Dunn's company. I don't</p> <p>8 know the details of his arrangement with the</p> <p>9 university. I just don't. He has a</p> <p>10 different type of appointment than I have.</p> <p>11 He doesn't do federally-funded research.</p> <p>12 That's what I know. I don't know the details</p> <p>13 of his arrangement with Vanderbilt.</p> <p>14 Q Is Dr. Dunn in a position of authority over</p> <p>15 you at Vanderbilt?</p> <p>16 A No.</p> <p>17 Q If Dr. Dunn wanted to do federally-funded</p> <p>18 research, would he be able to in light of his</p> <p>19 activities and the amount of money his</p> <p>20 company bills for expert work in the</p> <p>21 transvaginal mesh litigation?</p> <p>22 A I can't speak to that. I don't know how much</p> <p>23 his company bills or makes. I don't know</p> <p>24 that information.</p> <p>25 Q Have you investigated what affect your</p>	<p>1 disclosing conflicts to Vanderbilt since I</p> <p>2 started there. There is a very standard and</p> <p>3 routine process. Faculty are allowed and</p> <p>4 encouraged to participate in activities</p> <p>5 outside of Vanderbilt. I do this in the</p> <p>6 course of my research with licensing,</p> <p>7 start-up companies. This is routine.</p> <p>8 There is a process and a procedure. And</p> <p>9 we're not working around anything. We're</p> <p>10 trying to find a way to work within the</p> <p>11 framework of the federal regulations and</p> <p>12 university policy. It's very standard for</p> <p>13 universities.</p> <p>14 BY MR. SNELL:</p> <p>15 Q Have you told Vanderbilt how much money you</p> <p>16 have earned as an expert in the transvaginal</p> <p>17 mesh litigation?</p> <p>18 A You have asked me this before. And I said we</p> <p>19 are not required in the course of our work to</p> <p>20 disclose that. If I believe that I see a</p> <p>21 conflict between my research and the</p> <p>22 consulting, then I will disclose that and the</p> <p>23 university will -- we will have those</p> <p>24 discussions, but we are not required to</p> <p>25 disclose this information for consulting</p>

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<p>1 work.</p> <p>2 Q So the answer to my question is, no, you have</p> <p>3 not disclosed that to Vanderbilt, correct?</p> <p>4 A I'm not required -- strike that.</p> <p>5 Q My question is simple. Have you disclosed to</p> <p>6 Vanderbilt --</p> <p>7 A And I believe I have answered your question.</p> <p>8 Q I think you are telling me about what you're</p> <p>9 required to do.</p> <p>10 I'm asking you, have you, Dr. Guelcher,</p> <p>11 disclosed to Vanderbilt the monies, the</p> <p>12 amount of monies you have earned as a</p> <p>13 plaintiff's expert in transvaginal mesh</p> <p>14 litigation?</p> <p>15 MR. KUNTZ: Object. Answer it.</p> <p>16 BY MR. SNELL:</p> <p>17 Q It's a yes or no answer.</p> <p>18 A No, I've not disclosed, but I'm not --</p> <p>19 Q Have you informed your dean of your current</p> <p>20 intention to bill as an independent</p> <p>21 consultant to attorneys in the transvaginal</p> <p>22 mesh litigation?</p> <p>23 A Why would I inform the dean of this? I've</p> <p>24 not informed the dean. I have to inform the</p> <p>25 dean when I believe there is a conflict. And</p>	<p>1 if and when I submit a grant application,</p> <p>2 that would create the conflict, but that's</p> <p>3 tied to INH funding. That's not -- why I'm</p> <p>4 not required to disclose it unless there is a</p> <p>5 conflict of the federally-funded research</p> <p>6 project.</p> <p>7 Q Have you performed any testing on Ms. Perry's</p> <p>8 mesh?</p> <p>9 A I have not.</p> <p>10 Q Have you looked at Ms. Perry's mesh under a</p> <p>11 scanning electron microscope?</p> <p>12 A I have not.</p> <p>13 Q What are all of the different tests, methods</p> <p>14 that one can do to try to determine whether</p> <p>15 there is degradation of polypropylene?</p> <p>16 A So degradation of polypropylene could be</p> <p>17 assessed by SEM imaging. That's typically</p> <p>18 how we assess it.</p> <p>19 Q FTIR --</p> <p>20 A FTIR -- I'm sorry.</p> <p>21 Q FTIR is a way that one can go about trying to</p> <p>22 assess whether there is degradation of</p> <p>23 polypropylene, correct?</p> <p>24 A No, that's not why we use FTIR. We use FTIR</p> <p>25 to assess for oxidation, chemical changes in</p>
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<p>1 if and when I make that assessment, I will</p> <p>2 update my disclosure. But according to</p> <p>3 Vanderbilt policy, we're not required to do</p> <p>4 those things.</p> <p>5 Q Well, if you spent approximately 20 hours at</p> <p>6 \$285 an hour thus far, that is over \$5,000.</p> <p>7 Are you telling me that if you have a greater</p> <p>8 than \$5,000 interest in your role as an</p> <p>9 independent billing consultant to</p> <p>10 transvaginal mesh litigation, you do not need</p> <p>11 to tell that to the dean?</p> <p>12 MR. KUNTZ: Objection.</p> <p>13 A No, you are misinterpreting and</p> <p>14 misunderstanding what I have said. The</p> <p>15 question is, whether the proposed research,</p> <p>16 when I submit a grant application, I submit</p> <p>17 an application to the NIH for federal</p> <p>18 funding. I have to answer the question, do</p> <p>19 you have a significant financial interest in</p> <p>20 the outcome of this federally-funded project.</p> <p>21 Significant financial interest is defined</p> <p>22 as more than \$5,000. But at this point in</p> <p>23 time and in the past there -- at this time,</p> <p>24 there is no overlap between the consulting</p> <p>25 work and the federally-funded research. So</p>	<p>1 the polypropylene. That can be assessed by</p> <p>2 the FTIR.</p> <p>3 Q And when you look for oxidation via FTIR,</p> <p>4 what you are looking for is to see if there</p> <p>5 is a potential that would lead to</p> <p>6 degradation; is that correct?</p> <p>7 A No. We are looking at oxidation to answer</p> <p>8 the specific question of is the surface</p> <p>9 oxidizing, is it chemically changing. And we</p> <p>10 can see that by peaks in the FTIR spectra</p> <p>11 that are not there in the normal</p> <p>12 polypropylene, but do appear for oxidized</p> <p>13 polypropylene.</p> <p>14 Q Now, as I understand it, Dr. Dunn, in prior</p> <p>15 work did FTIR in connection with assessing</p> <p>16 the question of is there degradation of</p> <p>17 polypropylene?</p> <p>18 A And why is that -- I don't know what you're</p> <p>19 referring to.</p> <p>20 Q I recall in your Huskey testimony, in your</p> <p>21 deposition, you testified that all of the</p> <p>22 testing done was done by Dr. Dunn. And I</p> <p>23 believe you identified FTIR, XPS, and I don't</p> <p>24 know if there were others.</p> <p>25 A I don't remember the testing that Dr. Dunn</p>

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<p>1 did for the Huskey trial. I do believe we</p> <p>2 did FTIR. I don't remember the others, but</p> <p>3 oxidation and degradation are related, but</p> <p>4 they're -- in terms of -- and there may be</p> <p>5 times that people use the word degradation to</p> <p>6 consider all of these effects, but I'm</p> <p>7 speaking specifically about oxidation as a</p> <p>8 chemical process, and degradation as a</p> <p>9 physical one, and they're assessed by</p> <p>10 different techniques.</p> <p>11 And I don't remember all of the testing</p> <p>12 that Dr. Dunn did for the Huskey trial. I</p> <p>13 don't remember that.</p> <p>14 Q So if one does FTIR testing and sees that the</p> <p>15 surface is oxidized, that does not</p> <p>16 necessarily mean that the material is</p> <p>17 degraded, correct?</p> <p>18 A There are different tests to assess -- they</p> <p>19 could be degraded, but we would assess</p> <p>20 degradation using a different technique than</p> <p>21 FTIR. FTIR, as I said, is for chemical</p> <p>22 oxidation, which is a chemical change. There</p> <p>23 may be degradation, but we would confirm that</p> <p>24 with a technique such as SEM.</p> <p>25 Q So if a scientist has a positive FTIR finding</p>	<p>1 BY MR. SNELL:</p> <p>2 Q The fact that it's a strong indicator,</p> <p>3 though, that in and of itself means that</p> <p>4 there is some possibility that you will not</p> <p>5 see physical degradation, and there is a</p> <p>6 possibility as well that you will see it,</p> <p>7 physical degradation, if you look at SEM,</p> <p>8 correct?</p> <p>9 MR. KUNTZ: Objection.</p> <p>10 A Again, the literature tells us that you would</p> <p>11 expect degradation. Is it -- unless you</p> <p>12 actually see it, you can't prove -- you can't</p> <p>13 guarantee that it's there, but you would</p> <p>14 certainly expect it. It's within a</p> <p>15 reasonable degree of scientific certainty to</p> <p>16 expect that you would have degradation in</p> <p>17 time if that surface is being oxidized.</p> <p>18 There are numerous papers that teach</p> <p>19 about this, about polymers in general,</p> <p>20 polymers that are susceptible to oxidative</p> <p>21 attack showed signs of physical degradation.</p> <p>22 This was all worked out a number of years</p> <p>23 ago.</p> <p>24 MR. SNELL: Move to strike.</p> <p>25 BY MR. SNELL:</p>
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<p>1 for oxidation on the surface, he would then</p> <p>2 need to confirm that with SEM in order to</p> <p>3 reasonably say with scientific certainty that</p> <p>4 there was degradation?</p> <p>5 MR. KUNTZ: Objection.</p> <p>6 A I would say that the literature teaches us</p> <p>7 that these processes are related, oxidation.</p> <p>8 Chemical oxidation leads to physical</p> <p>9 degradation. And so if I see evidence of</p> <p>10 oxidation, I would expect to see physical</p> <p>11 degradation in time. To visibly see that</p> <p>12 physical degradation, I would do the</p> <p>13 technique such as SEM.</p> <p>14 But if I see oxidation, I would certainly</p> <p>15 expect based on published literature findings</p> <p>16 that there would be degradation in time to</p> <p>17 some extent.</p> <p>18 BY MR. SNELL:</p> <p>19 Q Well, if you see chemical oxidation, it is</p> <p>20 not a guarantee that physical degradation has</p> <p>21 taken place, correct?</p> <p>22 MR. KUNTZ: Objection.</p> <p>23 A I think I just answered that. It's a strong</p> <p>24 indicator that there is also physical</p> <p>25 degradation.</p>	<p>1 Q My question is this. It's straight forward.</p> <p>2 The fact that you see chemical oxidation,</p> <p>3 that does not mean that you would also see</p> <p>4 under SEM analysis physical degradation if</p> <p>5 you were to look at that particular time; is</p> <p>6 that correct?</p> <p>7 MR. KUNTZ: Objection. Asked</p> <p>8 and answered. Calls for speculation, and is</p> <p>9 an incomplete hypothetical. But go ahead.</p> <p>10 A This is a speculative question. What I'm</p> <p>11 saying is, if there is oxidative changes, the</p> <p>12 body of literature teaches within a</p> <p>13 reasonable degree of scientific certainty</p> <p>14 that there will be at some time physical</p> <p>15 degradation. That's what the literature is</p> <p>16 teaching us.</p> <p>17 BY MR. SNELL:</p> <p>18 Q You keep saying at some time there will be</p> <p>19 physical degradation. At what time will</p> <p>20 there be physical degradation?</p> <p>21 A As I've said in my previous testimony, it's</p> <p>22 unpredictable. And that's a problem for the</p> <p>23 design of the device, because it's subject to</p> <p>24 changes that can happen that you can't</p> <p>25 predict the timing of these changes and what</p>

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<p>1 the implications will be.</p> <p>2 Q Do you have an opinion as to what is the</p> <p>3 earliest point in time where there can be</p> <p>4 physical degradation of Ethicon's Prolene</p> <p>5 polypropylene used in TVT Abbrevio?</p> <p>6 A Again, that's a speculative question. I</p> <p>7 believe that upon implantation, the device</p> <p>8 will be colonized by adherent inflammatory</p> <p>9 cells. This is well-known in the literature,</p> <p>10 the foreign body reaction. Those cells will</p> <p>11 secrete species that oxidize it. The timing</p> <p>12 of all these events can depend on a number of</p> <p>13 factors, the nature of the inflammatory</p> <p>14 response where it's implanted, the mechanical</p> <p>15 stresses in the environment, whether there is</p> <p>16 a bacterial infection.</p> <p>17 The timing can be highly variable. It</p> <p>18 can happen early or it can happen late. The</p> <p>19 point is that it's unpredictable. That's</p> <p>20 what I've been saying.</p> <p>21 Q Well, I would like to know what does the</p> <p>22 literature teach you about the earliest point</p> <p>23 in time when you can say there is physical</p> <p>24 degradation of the Prolene polypropylene</p> <p>25 mesh?</p>	<p>1 time periods of three months and later.</p> <p>2 That's what Clave reported.</p> <p>3 Q And you have a list of materials here today.</p> <p>4 Where in Clave does it say that --</p> <p>5 A I would have to see the paper. I know that</p> <p>6 in Clave, it says that -- he notes that</p> <p>7 explants -- I would have to see it to give a</p> <p>8 precise answer. The number I remember is</p> <p>9 three months.</p> <p>10 (Deposition Exhibit No. 1 was</p> <p>11 marked for identification.)</p> <p>12 BY MR. SNELL:</p> <p>13 Q Doctor, I've handed you Exhibit No. 1. Is</p> <p>14 that the Clave paper you were referring to,</p> <p>15 sir?</p> <p>16 A That is correct.</p> <p>17 Q So can you show me where in Clave it states</p> <p>18 that physical degradation occurred in the</p> <p>19 Prolene polypropylene mesh at a certain time</p> <p>20 period?</p> <p>21 A I'm looking for that. So on Page 264 of</p> <p>22 Clave, it states degradation was observed</p> <p>23 only in samples implanted for at least three</p> <p>24 months.</p> <p>25 Q That is a general statement about the overall</p>
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<p>1 I don't want to rehash everything you</p> <p>2 talked about in Huskey. I know you talked</p> <p>3 about what was seen in two years and I</p> <p>4 believe five or seven years in a dog study</p> <p>5 and things like that. So with all of those</p> <p>6 principles that you've already testified</p> <p>7 about, let me just back up and re-ask it.</p> <p>8 A Okay.</p> <p>9 MR. KUNTZ: Objection.</p> <p>10 BY MR. SNELL:</p> <p>11 Q What is the earliest point in time that you</p> <p>12 can say that there is physical degradation of</p> <p>13 the Prolene polypropylene mesh?</p> <p>14 A I just can't answer that question. There are</p> <p>15 too many factors that can influence it. To</p> <p>16 say -- again, it's too speculative. It</p> <p>17 depends on many factors in addition to the</p> <p>18 chemical oxidation.</p> <p>19 Q Based on all of the literature that you saw,</p> <p>20 what was the earliest time reported that</p> <p>21 there was physical degradation of the Prolene</p> <p>22 polypropylene mesh?</p> <p>23 A For Prolene polypropylene, I can say from the</p> <p>24 Clave paper and the explants that were</p> <p>25 studied in Clave, he recorded degradation in</p>	<p>1 cohort of explants, correct?</p> <p>2 A That's my understanding.</p> <p>3 Q That statement is not necessarily particular</p> <p>4 to a Prolene polypropylene mesh implant,</p> <p>5 correct?</p> <p>6 A There could have been Prolene implants in</p> <p>7 this study. That statement doesn't specify</p> <p>8 whether that applies to Prolene or not.</p> <p>9 Q So my question is, can you point to any</p> <p>10 literature which informs you of the earliest</p> <p>11 time which the Prolene polypropylene mesh</p> <p>12 physically degrades?</p> <p>13 MR. KUNTZ: Objection.</p> <p>14 A I don't know of this -- you mean in vivo of</p> <p>15 patients?</p> <p>16 BY MR. SNELL:</p> <p>17 Q Yes, sir.</p> <p>18 A I don't know of a study that has specifically</p> <p>19 reported that.</p> <p>20 Q In the dog study -- and you're still relying</p> <p>21 on the dog study as well with the Prolene</p> <p>22 sutures?</p> <p>23 A The dog study, it's in my reliance materials,</p> <p>24 so it's part of the documents I have</p> <p>25 reviewed.</p>

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<p>1 Q At what point in time was physical 2 degradation observed in that study? 3 A I can't remember. I would have to look at 4 the document. 5 Q Okay. At a break, I would like for you to 6 look at that document. And I will have the 7 same question for the vascular graft Prolene 8 suture study, what is the earliest point in 9 that study if at any point in time it showed 10 physical degradation? 11 A Again, I would have to look at it. I don't 12 remember that level of detail. 13 Q Am I correct that although Clave reports 14 there were 100 explanted samples, a smaller 15 number were actually analyzed? 16 A What do you mean analyzed? I'm not sure what 17 you mean. 18 Q Let me ask you, how many explants were 19 analyzed in the Clave study? 20 A I would have to look at it. There were 100 21 explants. I'm still not sure what you're 22 asking, though. I mean, there were 100 23 explants. 24 Q How many of those 100 explants were actually 25 analyzed?</p>	<p>1 BY MR. SNELL: 2 Q My question was not what is he saying. My 3 question was to you, what limitations does 4 that place upon what one can draw from Clave 5 due to the fact that only 32 out of 100 6 explants were submitted for chemical testing? 7 A I don't see how it limits the finding that he 8 sees changes. That's what he is reporting, 9 whether he sees it in 32 or 50, whether he 10 looked at 32 or 100. I mean, you may be 11 implying that he was cherry-picking data, but 12 I have no reason to believe that. This is a 13 peer-reviewed journal. 14 I mean, he studied what he could study, 15 but it doesn't limit the finding that these 16 changes happened. Whether he did 32 or 100, 17 he still saw changes. So I don't understand 18 how that limits that finding. 19 Q Well, he had 100 explants, and he only 20 subjected 32 to chemical analysis. We can 21 agree to that, right? 22 A That's what he states. But beyond that, I 23 don't -- 24 Q And you don't know the methodology by which 25 he selected the particular 32 for chemical</p>
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<p>1 A Well, I think it depends on the method, so -- 2 they did a chemical analysis on 32 explants. 3 It doesn't necessarily say in the methods. 4 Q Why did Clave do less than one-third of the 5 overall sample size for chemical analysis? 6 A I don't know. I would have to look at this 7 to -- 8 Q By only analyzing 32 out of 100 explants for 9 a chemical analysis, what limitations does 10 that place upon the interpretation one can 11 draw from the Clave paper? 12 A Well, what I believe Clave is saying is 13 consistent with my opinions, that these 14 events can happen and can lead to problems 15 and complications. He's not saying it 16 happens all the time in every mesh at this 17 particular time. 18 He is saying that these meshes change, 19 which is consistent, which is my opinion in 20 this case, that the meshes change, and that 21 introduces an extra level of risk because 22 these changes make the meshes -- make their 23 behavior unpredictable. That is what he is 24 saying. 25 MR. SNELL: Move to strike.</p>	<p>1 analysis, correct? 2 A Well, let me read it. I need to read this, 3 because I'm not quite following where you are 4 going with this. 5 Okay. So he says -- I mean, he explains 6 himself. The samples were divided into four 7 groups. Because of the small sample size and 8 physical condition of the explanted 9 materials, extensive and complete chemical 10 analysis was difficult, which I think most 11 would agree is true. And he has several 12 groups listed here, four groups. 13 One of the fourth group is a control with 14 pristine implants, which he has a number of 15 pristine implants listed. So he grouped one 16 as degraded polypropylene that he analyzed by 17 SEM. 18 Group two is a group of nondegraded 19 explants, which again looks like 20 polypropylene mesh. And then the fourth 21 group of PET explants. That's what he says 22 he did. And he says it was difficult. He 23 probably didn't have much material to work 24 with, but these are explants. This isn't a 25 clinical trial. These are explants, so that</p>

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<p>1 is what he had to work with.</p> <p>2 Q But do you know then the methodology by which</p> <p>3 he determined the cut point for whether it</p> <p>4 was too difficult or not to do SEM analysis?</p> <p>5 A He doesn't provide more detail, but this is</p> <p>6 what I understand that he did.</p> <p>7 Q So we have no way of knowing what chemical</p> <p>8 analysis would have shown for those 68</p> <p>9 explants that were not subjected to chemical</p> <p>10 analysis; is that fair?</p> <p>11 A Say that again. I didn't catch it.</p> <p>12 Q Sure.</p> <p>13 We do not know what, if anything, would</p> <p>14 have been shown for the 68 other explants</p> <p>15 that were not subjected to chemical analysis</p> <p>16 because the chemical analyses were not done;</p> <p>17 is that fair?</p> <p>18 A We don't know. He didn't report it, for</p> <p>19 reasons that I'm not entirely sure.</p> <p>20 Q And in Clave's paper, am I correct that not</p> <p>21 all of the polypropylene explants were even</p> <p>22 -- had physical degradation?</p> <p>23 A Yes. But I talked about this earlier, Clave</p> <p>24 is not trying to report the incidents of --</p> <p>25 strike that. He's not trying to report</p>	<p>1 it as, wow, one-third were degraded, that's a</p> <p>2 lot. That's how I look at it.</p> <p>3 Q Regardless of how you want to characterize</p> <p>4 it, let's see if we can agree to this.</p> <p>5 Dr. Guelcher, we can both agree that</p> <p>6 Dr. Clave reported that the rate of</p> <p>7 degradation in the polypropylene monofilament</p> <p>8 was one-third or 33.33 percent, correct?</p> <p>9 A That's what he reported. But to try to</p> <p>10 construe that that is a good number is beyond</p> <p>11 my understanding. That's what he reported.</p> <p>12 He reported that one-third were degraded.</p> <p>13 MR. SNELL: Move to strike. I'm</p> <p>14 just looking for a yes or no.</p> <p>15 BY MR. SNELL:</p> <p>16 Q If we can agree to this basic fact. How you</p> <p>17 characterize it, I know what position you're</p> <p>18 coming from. All right.</p> <p>19 In the Clave paper for the polypropylene</p> <p>20 monofilament, the rate of degradation seen</p> <p>21 was one out of three or 33.33 percent,</p> <p>22 correct?</p> <p>23 A That's what's in the table.</p> <p>24 Q Fair enough.</p> <p>25 And you have your interpretation of that?</p>
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<p>1 frequency. He is saying that he observed it.</p> <p>2 With what he had, with what he could test, he</p> <p>3 observed evidence. He doesn't say he</p> <p>4 observed it in every sample, but he did</p> <p>5 observe it. That's what he is saying. So he</p> <p>6 did not observe it in every sample, but we've</p> <p>7 talked about this.</p> <p>8 Q Dr. Clave did report the rate of degradation</p> <p>9 that he saw in the samples that he actually</p> <p>10 did analyze, correct?</p> <p>11 A He did report that number but --</p> <p>12 Q So for polypropylene monofilament at the</p> <p>13 table at the top of Page 266, do you see</p> <p>14 that?</p> <p>15 A I see that number. I know what you're</p> <p>16 saying.</p> <p>17 Q And you understand the Prolene polypropylene</p> <p>18 mesh in the TVT Abbrevio to be a monofilament</p> <p>19 polypropylene?</p> <p>20 A Yes.</p> <p>21 Q And what Clave found was that only one-third</p> <p>22 of that sample of polypropylene monofilament</p> <p>23 that he actually looked at was degraded,</p> <p>24 correct?</p> <p>25 A I look at it a little differently. I look at</p>	<p>1 A I do.</p> <p>2 Q And let me ask you, if more likely than not</p> <p>3 it's 51 percent or higher, you can't look at</p> <p>4 the Clave paper and say it's more likely than</p> <p>5 not that there would be degradation to</p> <p>6 polypropylene monofilament mesh, correct?</p> <p>7 MR. KUNTZ: Objection. You can</p> <p>8 answer.</p> <p>9 A If I were a patient looking at that number, I</p> <p>10 would be concerned.</p> <p>11 MR. SNELL: Move to strike.</p> <p>12 Nonresponsive.</p> <p>13 BY MR. SNELL:</p> <p>14 Q When you look the Clave paper, you can't say</p> <p>15 it's more likely than not that there was</p> <p>16 degradation to the polypropylene monofilament</p> <p>17 mesh, correct?</p> <p>18 MR. KUNTZ: Objection.</p> <p>19 A I don't even know how to answer that</p> <p>20 question. I mean, it's -- he reported 33</p> <p>21 percent. I will agree that he reported that</p> <p>22 in this table, in table two, he reports -- or</p> <p>23 figure two, he reports that 33 percent were</p> <p>24 degraded. Beyond that, I can't -- that's</p> <p>25 what he says.</p>

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<p style="text-align: right;">Page 58</p> <p>1 BY MR. SNELL:</p> <p>2 Q So you would agree that Dr. Clave's paper in</p> <p>3 this table and report, that it's more likely</p> <p>4 than not that the mesh was actually not found</p> <p>5 to be degraded, correct?</p> <p>6 A I cannot answer that question. That doesn't</p> <p>7 make any sense. I mean, this is what he</p> <p>8 reported. To try to construe that -- that's</p> <p>9 what he reported and what he tested. To try</p> <p>10 to construe more out of this, this wasn't a</p> <p>11 controlled study where he was trying to</p> <p>12 measure rate of degradation. He made</p> <p>13 observations and he reported a number, this</p> <p>14 percentage that I saw to be degraded.</p> <p>15 He was not aiming to estimate some -- he</p> <p>16 is just reporting. This is the way I read</p> <p>17 this paper. So I can't answer this question</p> <p>18 that it's more likely than not on anything.</p> <p>19 That's just the number he provides.</p> <p>20 Q So the Clave paper we can agree does not</p> <p>21 stand for the proposition that it's more</p> <p>22 likely than not that polypropylene</p> <p>23 monofilament is degraded?</p> <p>24 MR. KUNTZ: Objection.</p> <p>25 A I can't agree to this line of questioning.</p>	<p style="text-align: right;">Page 60</p> <p>1 That's what I'm saying. Unpredictable means</p> <p>2 you can't predict, and that's a problem.</p> <p>3 That's why the design is flawed is because</p> <p>4 you can't predict. The changes can happen,</p> <p>5 and you can't predict when or the</p> <p>6 implications of those changes.</p> <p>7 My simple point is that Clave sees those</p> <p>8 events and reports them, but this is not a</p> <p>9 study designed to investigate the number of</p> <p>10 meshes that got -- that were degraded.</p> <p>11 That's not what he is saying. He is</p> <p>12 observing -- he is reporting an observation.</p> <p>13 I think you're misinterpreting. You're</p> <p>14 trying to put me in a position to</p> <p>15 misinterpret Clave, and I can't do that. I</p> <p>16 can only report on what I see.</p> <p>17 BY MR. SNELL:</p> <p>18 Q So you can only report that for the samples</p> <p>19 that Clave did decide to analyze for</p> <p>20 degradation, it was 33.33 percent for the</p> <p>21 polypropylene monofilament, and to try to</p> <p>22 take that number and extrapolate it is not</p> <p>23 something you're willing to do?</p> <p>24 MR. KUNTZ: Objection.</p> <p>25 A When have I done that in trial testimony?</p>
<p style="text-align: right;">Page 59</p> <p>1 This is -- why can't we not just agree that</p> <p>2 -- I agree this is what he reported. And</p> <p>3 beyond that, I'm not going to agree to any</p> <p>4 other interpretation of that number. That's</p> <p>5 what he reports. It's an observation saying</p> <p>6 that this can happen, which is what I've been</p> <p>7 saying in my trial and deposition testimony,</p> <p>8 that these events can happen and Clave</p> <p>9 observed it. That's what it says.</p> <p>10 Q So you believe these events of degradation</p> <p>11 can happen, and Clave observed it in</p> <p>12 one-third of the sample, correct?</p> <p>13 A He observed it in 33 percent of the samples</p> <p>14 that he tested.</p> <p>15 Q And an expert can take Clave and say, because</p> <p>16 it was seen in Clave, and it was seen in</p> <p>17 33.33 percent, that means that all meshes</p> <p>18 will be degraded, correct?</p> <p>19 MR. KUNTZ: Objection. Asked</p> <p>20 and answered.</p> <p>21 A But I've not been saying that. I've been</p> <p>22 saying specifically that oxidation and</p> <p>23 degradation can occur in these meshes, and it</p> <p>24 can lead to adverse events. The timing of</p> <p>25 when -- these things are unpredictable.</p>	<p style="text-align: right;">Page 61</p> <p>1 You've seen my depositions.</p> <p>2 MR. SNELL: Move to strike.</p> <p>3 BY MR. SNELL:</p> <p>4 Q We are going to be here all day. I'm not</p> <p>5 asking about when did I see you doing</p> <p>6 something. I'm really not.</p> <p>7 A I just feel like you're covering old ground</p> <p>8 that I've been over so many times, and you're</p> <p>9 trying to get me to misrepresent a paper that</p> <p>10 I've testified about so many times. And I</p> <p>11 don't understand why you're doing that.</p> <p>12 That's why I'm frustrated.</p> <p>13 Q Well, it's a simple yes or no answer.</p> <p>14 A But the questions are convoluted. And the</p> <p>15 way you're asking them is implying certain</p> <p>16 things. When you say he decided to analyze.</p> <p>17 Why could we not say, Clave analyzed -- in</p> <p>18 the number of samples that Clave estimated by</p> <p>19 SEM, he observed 33 percent of them were</p> <p>20 degraded. I agree with that. That's what</p> <p>21 Clave says.</p> <p>22 But I don't want to agree to any other</p> <p>23 questions that infer some kind of intent or</p> <p>24 something in Clave. That's what I'm</p> <p>25 resisting. I'm not trying to be difficult.</p>

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<p>1 I just feel like I have been very clear about</p> <p>2 what I think about this paper. And I'm just</p> <p>3 saying that it is consistent with my</p> <p>4 testimony that these events can happen.</p> <p>5 That's what I am saying. That's what I have</p> <p>6 always been saying.</p> <p>7 Q I just want to get an answer to my question.</p> <p>8 You interpret Clave as being consistent</p> <p>9 with your opinion in that it can happen. And</p> <p>10 Clave observed it in 33.33 percent, correct?</p> <p>11 A Yes, he observed it in 33 percent, that's</p> <p>12 fine.</p> <p>13 Q But you not take Clave and extrapolate Clave</p> <p>14 to say that a certain rate of degradation</p> <p>15 will be seen in the mesh samples? Yes or no.</p> <p>16 MR. KUNTZ: Asked and answered.</p> <p>17 Eight times.</p> <p>18 A I've not done that and I'm not doing that</p> <p>19 now.</p> <p>20 BY MR. SNELL:</p> <p>21 Q Okay. That's all I wanted to know was is</p> <p>22 that something you would do or would not do.</p> <p>23 A Well, where you ended up with the question, I</p> <p>24 was fine with it. I'm not trying to be</p> <p>25 difficult. I'm sorry.</p>	<p>1 there is no case specific depositions on</p> <p>2 there.</p> <p>3 MR. SNELL: Well, that is what I</p> <p>4 was going to say.</p> <p>5 BY MR. SNELL:</p> <p>6 Q So, Dr. Guelcher, I looked at your reliance</p> <p>7 list. It's on the thumb drive. And I didn't</p> <p>8 see any case specific depositions,</p> <p>9 particularly from Mrs. Perry's case. Is that</p> <p>10 consistent or inconsistent with your</p> <p>11 knowledge?</p> <p>12 A I have -- it's consistent with my knowledge,</p> <p>13 yeah.</p> <p>14 Q You're not relying on any case specific</p> <p>15 depositions in the Perry case for your</p> <p>16 opinions are you, sir?</p> <p>17 A I am not.</p> <p>18 Q All right. Thank you.</p> <p>19 A Okay.</p> <p>20 Q Earlier we were talking about some testing.</p> <p>21 And you didn't do any SEM testing on</p> <p>22 Mrs. Perry's explant, correct?</p> <p>23 A No, I did not.</p> <p>24 Q Did you have anybody else do any testing of</p> <p>25 Mrs. Perry's explant on your behalf?</p>
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<p>1 MR. SNELL: All right. Let's</p> <p>2 take a break.</p> <p>3 (A brief recess was taken from</p> <p>4 10:40 to 10:50 a.m.)</p> <p>5 BY MR. SNELL:</p> <p>6 Q Doctor, you didn't look at Mrs. Perry's</p> <p>7 medical records, correct?</p> <p>8 A I did not look at her records.</p> <p>9 Q Did you look at any of the depositions taken</p> <p>10 in Mrs. Perry's case, hers or any of her</p> <p>11 doctors or family members?</p> <p>12 A I looked at some depositions, but I can't</p> <p>13 remember exactly those -- I don't know.</p> <p>14 Q Are you certain that they were depositions in</p> <p>15 the Perry case or could they have been from</p> <p>16 some other matter?</p> <p>17 A It could have been. There has been so many</p> <p>18 cases, it's hard for me to keep all of the</p> <p>19 documents straight.</p> <p>20 Q I'm looking at your reliance list, and I gave</p> <p>21 you this back.</p> <p>22 A The reliance list?</p> <p>23 Q Your list of materials on there that you</p> <p>24 provided --</p> <p>25 MR. KUNTZ: I will tell you that</p>	<p>1 A I did not.</p> <p>2 Q Okay. You didn't do any FTIR testing on</p> <p>3 Mrs. Perry's explant, correct?</p> <p>4 A I did not.</p> <p>5 Q Did you do any GPC testing on Mrs. Perry's</p> <p>6 explant?</p> <p>7 A No. The only explant I received was in the</p> <p>8 form of sections of the slides of tissue, so</p> <p>9 it's -- I didn't do any of this type of</p> <p>10 testing on that material.</p> <p>11 Q You did not do XPS testing on Mrs. Perry's</p> <p>12 mesh, correct?</p> <p>13 A That's correct.</p> <p>14 Q You did not do DSC testing on Mrs. Perry's</p> <p>15 mesh, correct?</p> <p>16 A No.</p> <p>17 Q You did not do EDX testing on Mrs. Perry's</p> <p>18 mesh; is that correct?</p> <p>19 A That's correct.</p> <p>20 Q Are there any tests besides SEM, FTIR, GPC,</p> <p>21 XPS, DSC and EDX that someone can do to look</p> <p>22 for either chemical or structural</p> <p>23 degradation?</p> <p>24 A So Dr. Iakovlev, who has testified in other</p> <p>25 litigation, not in this particular case I</p>

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<p>1 don't believe, but he has a microscopic</p> <p>2 method for evaluating degradation of the mesh</p> <p>3 by microscopy.</p> <p>4 Q Dr. Iakovlev is a pathologist as you</p> <p>5 understand it?</p> <p>6 A He is a pathologist at a hospital in Toronto.</p> <p>7 Q And Dr. Iakovlev is not an expert in this</p> <p>8 case to your knowledge; is that correct?</p> <p>9 A To my knowledge. I've not discussed this</p> <p>10 case with Dr. Iakovlev.</p> <p>11 Q Do you know if Dr. Iakovlev has looked at</p> <p>12 Mrs. Perry's mesh or slides?</p> <p>13 MR. KUNTZ: Objection.</p> <p>14 A Not to my knowledge.</p> <p>15 BY MR. SNELL:</p> <p>16 Q Do you know if Dr. Iakovlev's microscopic</p> <p>17 method for evaluating mesh has been analyzed</p> <p>18 by any of the pathology medical societies,</p> <p>19 like the American Association of Surgical</p> <p>20 Pathologists or the American College of</p> <p>21 Pathology?</p> <p>22 A I don't know the answer to that. But we are</p> <p>23 preparing a manuscript on explaining mesh</p> <p>24 that will be submitted soon. And I'm a</p> <p>25 co-author on that manuscript.</p>	<p>1 manuscript.</p> <p>2 Q As you sit here today, is it correct, sir,</p> <p>3 that you do not know the particular patients</p> <p>4 for whom those slides were made that are</p> <p>5 going to be the subject of this manuscript?</p> <p>6 A That is correct. I do not know their</p> <p>7 identity.</p> <p>8 Q Okay. Actually, some slides from Mrs. Perry</p> <p>9 were brought to the deposition today,</p> <p>10 correct?</p> <p>11 A That's correct.</p> <p>12 Q Have you looked at those slides?</p> <p>13 A I looked at them visually, but I did not look</p> <p>14 at them under the microscope.</p> <p>15 Q Okay. Now, the Perry slides that you looked</p> <p>16 at visually, how did you come to obtain</p> <p>17 those?</p> <p>18 A Through plaintiff's counsel.</p> <p>19 Q You didn't get those through from</p> <p>20 Dr. Iakovlev?</p> <p>21 A No, I did not. Plaintiff's counsel.</p> <p>22 Q And you have not sent Mrs. Perry's slides to</p> <p>23 Dr. Iakovlev, correct?</p> <p>24 A I received the slides from Plaintiff's</p> <p>25 counsel, and they have been in my possession</p>
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<p>1 Q Does this manuscript concern Mrs. Perry's</p> <p>2 explant to your knowledge?</p> <p>3 A I am not aware of Dr. Iakovlev -- strike</p> <p>4 that. From my perspective, the patients are</p> <p>5 de-identified. I don't know the identity of</p> <p>6 any patients in that study. What</p> <p>7 Dr. Iakovlev knows, I don't know.</p> <p>8 Q And were these explanted meshes received by</p> <p>9 you or Vanderbilt or were they received by</p> <p>10 Dr. Iakovlev or someone else?</p> <p>11 A They were all received by Dr. Iakovlev from</p> <p>12 varying sources. And all of those details,</p> <p>13 he knows. I did not handle the specific</p> <p>14 materials. I was never involved in that.</p> <p>15 Q For this testing, who did the testing that is</p> <p>16 going to be the subject of this manuscript?</p> <p>17 A So Dr. Iakovlev did the testing. My</p> <p>18 contribution was suggesting disdain for</p> <p>19 myeloperoxidase, which is a marker for</p> <p>20 reactive oxygen. And that information is</p> <p>21 concluded and discussed in the manuscript.</p> <p>22 And I have assisted Dr. Iakovlev with</p> <p>23 revising and editing the manuscript.</p> <p>24 I have made my changes and sent these to</p> <p>25 him. And that's been my role in the</p>	<p>1 since.</p> <p>2 Q Okay. When did you receive those slides that</p> <p>3 are particular to Mrs. Perry?</p> <p>4 A A few weeks ago maybe. I don't remember</p> <p>5 exactly.</p> <p>6 Q What is this myeloperoxidase stain that you</p> <p>7 referenced earlier?</p> <p>8 A It's myeloperoxidase. It's spelled</p> <p>9 M-Y-E-L-O-P-E-R-O-X-I-D-A-S-E.</p> <p>10 Q And what is the purpose of the</p> <p>11 myeloperoxidase stain?</p> <p>12 A So myeloperoxidase is an enzyme that converts</p> <p>13 hydrogen peroxide and other substrates to</p> <p>14 hydroxyl radicals and other forms of reactive</p> <p>15 oxygen species. And so if we see a stain</p> <p>16 that is positive for myeloperoxidase, that</p> <p>17 tells us that the inflammatory cells are</p> <p>18 secreting reactive oxygen species, that the</p> <p>19 mesh is being exposed to the reactive oxygen</p> <p>20 species and would therefore be a marker of</p> <p>21 this initiation of events of oxidation and</p> <p>22 degradation. That's the purpose of the</p> <p>23 stain.</p> <p>24 Q Okay. To your knowledge, Mrs. Perry's</p> <p>25 pathology slides have not been stained with</p>

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<p>1 this myeloperoxidase stain; is that correct?</p> <p>2 A That's my understanding.</p> <p>3 Q So as I understand it, the myeloperoxidase</p> <p>4 stain --</p> <p>5 A You can call it MPO.</p> <p>6 Q Thank you. That makes it a lot easier.</p> <p>7 The MPO stain is a stain that one can do</p> <p>8 to look for reactive oxygen?</p> <p>9 A That's correct. I published two papers on</p> <p>10 this in my work at Vanderbilt. So it's a</p> <p>11 routine essay.</p> <p>12 Q And reactive oxygen is what these</p> <p>13 inflammatory cells secrete or can secrete; is</p> <p>14 that correct?</p> <p>15 A So the Dr. Anderson review that's in my</p> <p>16 reliance materials from the 2008 seminars in</p> <p>17 immunology teaches that within days of</p> <p>18 implantation, the biomaterial, including</p> <p>19 polypropylene, including Prolene mesh, is</p> <p>20 colonized by these inflammatory cells that</p> <p>21 adhere to the surface. And the enzymes that</p> <p>22 they secrete, such as MPO, are these --</p> <p>23 result in the formation of reactive oxygen</p> <p>24 species to which the surface of the material</p> <p>25 is exposed.</p>	<p>1 counsel. So just to clarify your question,</p> <p>2 the slides as I received them to my knowledge</p> <p>3 were not stained for MPO, and so that</p> <p>4 assessment could not be made. It could be</p> <p>5 possible to do that work, but that's a</p> <p>6 decision for the attorneys to work out, not</p> <p>7 me.</p> <p>8 Q All right. To your understanding, it could</p> <p>9 be possible that plaintiff's counsel could</p> <p>10 have those slides stained for MPO, correct?</p> <p>11 A It's a complicated question how these samples</p> <p>12 are handled, whether or not they're in the</p> <p>13 right form that it can be done. I would</p> <p>14 think we would need the blocks to cut new</p> <p>15 slides. I don't know what material is</p> <p>16 available. I would say in theory it could be</p> <p>17 done, but I don't know how practical that is.</p> <p>18 I don't know the history of the slides,</p> <p>19 that's the history of the explants.</p> <p>20 Q You would not be the one looking at the</p> <p>21 slides under the microscope if an MPO stain</p> <p>22 was done in any event?</p> <p>23 A I would. I would look at that under the</p> <p>24 microscope and I would take a picture. My</p> <p>25 students have done that in the past. But</p>
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<p>1 That's what's happening. That's what I</p> <p>2 have testified to in the past.</p> <p>3 Q Okay. We can't say in Mrs. Perry's case that</p> <p>4 there is MPO at the site of her mesh,</p> <p>5 correct?</p> <p>6 A I would say that with a reasonable degree of</p> <p>7 scientific certainty, he's talking about</p> <p>8 Anderson's 2008 paper. Adherent macrophages,</p> <p>9 when they adhere, they become activated, and</p> <p>10 they begin to secrete ROS or reactive oxygen</p> <p>11 species. And the explants that Dr. Iakovlev</p> <p>12 has looked at, he has seen myeloperoxidase</p> <p>13 staining in the ones that he's stained.</p> <p>14 And so from a reasonable degree of</p> <p>15 scientific certainty, I would expect to see</p> <p>16 myeloperoxidase, but we did not -- those</p> <p>17 stains, those slides to my knowledge have not</p> <p>18 been stained for MPO, and so I could not</p> <p>19 assess that.</p> <p>20 Q Is it fair to say you could not assess in the</p> <p>21 Perry case MPO's presence at the mesh; is</p> <p>22 that correct?</p> <p>23 A I don't think I like the words could not.</p> <p>24 They could be stained. This work could be</p> <p>25 done, but that's a decision for plaintiff's</p>	<p>1 this is evidence, I'm not going to just take</p> <p>2 those slides and stain them for MPO not</p> <p>3 knowing their history. There are legal</p> <p>4 ramifications to that. You know, both sides</p> <p>5 have to agree to testing procedures.</p> <p>6 This is a complicated question. All I'm</p> <p>7 saying is that to my knowledge these are H&E</p> <p>8 sections. And to assess the presence of</p> <p>9 myeloperoxidase, they would need to be</p> <p>10 stained.</p> <p>11 Q To assess the presence of MPO, the slides</p> <p>12 would need to be stained?</p> <p>13 A To confirm it. I need to be very clear what</p> <p>14 I'm saying. Based on a reasonable degree of</p> <p>15 scientific certainty, my work with</p> <p>16 Dr. Iakovlev, my reading of the literature, I</p> <p>17 would fully expect to see positive stain from</p> <p>18 myeloperoxidase. That has not been visibly</p> <p>19 confirmed in a section because the slides</p> <p>20 have not stained for that enzyme.</p> <p>21 Q What is the literature that you are</p> <p>22 referencing with regard to your opinion that</p> <p>23 you would expect the MPO stain to be positive</p> <p>24 if it was done in Mrs. Perry's case?</p> <p>25 A The paper that comes to mind would be a</p>

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<p>1 review paper by Professor Jim Anderson at</p> <p>2 Case Western from 2008 where he cites a very</p> <p>3 large number of papers in this review.</p> <p>4 And he teaches that upon implantation,</p> <p>5 the surface is colonized by these monocytes,</p> <p>6 inflammatory cells, that differentiate in the</p> <p>7 macrophages, foreign body giant cells, and</p> <p>8 become activated when they adhere to that</p> <p>9 surface and secrete reactive oxygen species,</p> <p>10 such as myeloperoxidase or they produce.</p> <p>11 Q This work by Dr. Iakovlev, has it been</p> <p>12 published anywhere that you have seen, in a</p> <p>13 peer-reviewed journal?</p> <p>14 A It's not been published. We're preparing to</p> <p>15 submit it, the manuscript. It's not been</p> <p>16 published yet, though. It's still a</p> <p>17 confidential work product that will be</p> <p>18 submitted.</p> <p>19 Q Do you have a copy of the manuscript on the</p> <p>20 thumb drive?</p> <p>21 A No. It's a confidential work product with</p> <p>22 Dr. Iakovlev, so we have to maintain strict</p> <p>23 confidentiality when we submit to the</p> <p>24 journals so we don't compromise the review</p> <p>25 process.</p>	<p>1 Q How large of a cohort is this?</p> <p>2 A 130 patients, explants from 130 patients.</p> <p>3 Q And this is a cohort for whom you do not know</p> <p>4 which patients are particularly involved?</p> <p>5 A I am blind to patient identity.</p> <p>6 Q Okay. Would it be fair to say you do not</p> <p>7 know which manufacturer's meshes are involved</p> <p>8 for whichever particular patient in that</p> <p>9 study?</p> <p>10 A I believe that in the manuscript,</p> <p>11 Dr. Iakovlev mentions some of the devices,</p> <p>12 but I don't know which device went in which</p> <p>13 patient. And I don't know if Dr. Iakovlev</p> <p>14 has that information.</p> <p>15 Q As you sit here, you do not personally have</p> <p>16 knowledge about what device went into which</p> <p>17 patient?</p> <p>18 A I do not.</p> <p>19 Q As you sit here, you do not personally know</p> <p>20 which particular manufacturer's devices were</p> <p>21 the subject of the 130 patients?</p> <p>22 A I believe I have that information. It may be</p> <p>23 in the manuscript. I just can't remember. I</p> <p>24 don't remember. That information may be in</p> <p>25 the manuscript, but certainly I don't know</p>
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<p>1 Q Do you know the rate at which the MPO</p> <p>2 standing was positive in the samples that</p> <p>3 Dr. Iakovlev did?</p> <p>4 A When you say rate, I think you mean</p> <p>5 frequency?</p> <p>6 Q Sure.</p> <p>7 A From my understanding, all of the explants</p> <p>8 that I've seen from Dr. Iakovlev stained</p> <p>9 positive for myeloperoxidase. So I'm not</p> <p>10 saying that everything I've seen is positive</p> <p>11 for myeloperoxidase.</p> <p>12 Q These are other litigation explants, correct?</p> <p>13 A In some cases. I have seen explants from</p> <p>14 Dr. Iakovlev for other litigation, and there</p> <p>15 is also the manuscript. So I should say, the</p> <p>16 explants that I've seen stain for</p> <p>17 myeloperoxidase from Dr. Iakovlev. All have</p> <p>18 tested positive for myeloperoxidase or MPO.</p> <p>19 Q Do you have those explants or samples in your</p> <p>20 possession?</p> <p>21 A I do not. That's Dr. Iakovlev's work</p> <p>22 product. I've seen -- Dr. Iakovlev has sent</p> <p>23 me images, pictures of the slides that I've</p> <p>24 included in expert reports in previous</p> <p>25 testimony.</p>	<p>1 which device was with which patient. I would</p> <p>2 not know that because I don't know the</p> <p>3 patients.</p> <p>4 Q You don't have personal knowledge such that</p> <p>5 you have confirmed that a particular</p> <p>6 manufacturer's device was the subject of the</p> <p>7 130-patient study, correct?</p> <p>8 A Yeah, I can't disclose that right now. I</p> <p>9 can't even remember it. I'm just saying for</p> <p>10 the record, it may be in the manuscript, but</p> <p>11 I don't remember those devices.</p> <p>12 Q If it may be in the manuscript, it's</p> <p>13 something that Dr. Iakovlev would have put in</p> <p>14 there and not you?</p> <p>15 A Yes, that's fair.</p> <p>16 Q So you don't have personal knowledge, you've</p> <p>17 been relying on what Dr. Iakovlev said, if</p> <p>18 indeed he even said it in the manuscript,</p> <p>19 correct?</p> <p>20 A That's correct.</p> <p>21 Q So I guess you would not know if there were</p> <p>22 any TVT Abbrevos that were the subject of</p> <p>23 this manuscript?</p> <p>24 A I don't remember. But I'm not relying on the</p> <p>25 manuscript for my opinions in this case,</p>

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<p>1 because it's not been published yet, and</p> <p>2 we're not disclosing it, so --</p> <p>3 Q Okay.</p> <p>4 A You're asking me about my experience with</p> <p>5 mesh and I'm telling you. That's my</p> <p>6 understanding.</p> <p>7 Q Fair enough.</p> <p>8 You're not relying on that manuscript in</p> <p>9 the 130-patient analysis for your opinions in</p> <p>10 this case, in the Perry case?</p> <p>11 A Yes, I would say those findings confirm my</p> <p>12 opinions, but I am not relying on them</p> <p>13 because that manuscript is still a work in</p> <p>14 progress.</p> <p>15 Q So when the inflammatory cell attaches to the</p> <p>16 mesh or to a foreign body, MPO is one of the</p> <p>17 substances it can release?</p> <p>18 A Well, I would say that MPO is an enzyme in</p> <p>19 the cell that catalyzes the reaction of</p> <p>20 substrates, such as peroxides, to form,</p> <p>21 reactive oxygen species such as, you know,</p> <p>22 hydroxyl radicals, superoxide. There is a</p> <p>23 very large number of these reactive oxygen</p> <p>24 species, but MPO is an enzyme that generates</p> <p>25 those reactive oxygen species.</p>	<p>1 and the properties change very dramatically.</p> <p>2 But degradation can occur prior to induction,</p> <p>3 and it certainly can occur after induction,</p> <p>4 so the two processes are related.</p> <p>5 The mechanical stresses can certainly</p> <p>6 impact this as well. That's known as</p> <p>7 environmental stress cracking. So they are a</p> <p>8 factor, so you can't separate the two. The</p> <p>9 mechanical stresses and the chemical stresses</p> <p>10 are interrelated.</p> <p>11 Q You've not seen any embrittlement of</p> <p>12 Mrs. Perry's mesh, correct?</p> <p>13 A I have not tested for it and have not seen</p> <p>14 it.</p> <p>15 Q You've not seen any cracking of Mrs. Perry's</p> <p>16 mesh, correct?</p> <p>17 A Correct. I haven't tested for it and seen</p> <p>18 it.</p> <p>19 Q You have not seen any molecular weight loss</p> <p>20 from Mrs. Perry's mesh, correct?</p> <p>21 A No. I've not tested for that and seen it.</p> <p>22 Q Besides the macrophages, are there any other</p> <p>23 cells that you will plan to testify can</p> <p>24 release these reactive oxygen species?</p> <p>25 A Well, Dr. Anderson teaches that monocytes,</p>
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<p>1 Q It's your opinion that the reactive oxygen</p> <p>2 species produce compounds, chemicals, which</p> <p>3 has an affect on the mesh?</p> <p>4 A So the reactive oxygen species do impact the</p> <p>5 mesh. They -- through this oxidation</p> <p>6 chemistry of polypropylene, the tertiary</p> <p>7 carbon hydrogen bond is subject to attack,</p> <p>8 and those radicals will attack that bond and</p> <p>9 oxidize the polypropylene.</p> <p>10 Q If the radicals don't attack the bond, does</p> <p>11 the polypropylene get oxidized?</p> <p>12 A It may be other mechanisms. The most</p> <p>13 well-known is this radical attack.</p> <p>14 Q Are you going to come in and testify that</p> <p>15 there are other methods by which the</p> <p>16 polypropylene gets degraded besides this, you</p> <p>17 know, attacking the bond that you've talked</p> <p>18 about? I don't see it here in your summary</p> <p>19 of opinions.</p> <p>20 A So in my summary of opinions, I discussed the</p> <p>21 interactions between oxidation and</p> <p>22 degradation. And my point is that oxidation</p> <p>23 as we're saying is a very early event. It</p> <p>24 happens immediately upon implantation. And</p> <p>25 at some point, the materials become induced,</p>	<p>1 which are very small mononuclear cells,</p> <p>2 colonize the implant, and then those cells --</p> <p>3 and they adhere to the implant. And when</p> <p>4 they attach or adhere to the surface of the</p> <p>5 implant, they become activated. They can</p> <p>6 differentiate to become macrophages or</p> <p>7 macrophages can fuse to form foreign body</p> <p>8 giant cells.</p> <p>9 And these cells all come from a common</p> <p>10 lineage, so they're all inflammatory cells.</p> <p>11 So when they're adhered, they're activated to</p> <p>12 secrete ROS. Other types of cells, such as</p> <p>13 neutrophils, which is commonly seen during</p> <p>14 acute inflammation or infection, also secrete</p> <p>15 ROS. So there are other cell populations.</p> <p>16 Really just many, many types of cells secrete</p> <p>17 ROS. But in my previous testimony, I was</p> <p>18 focusing specifically about these adherent</p> <p>19 macrophages in giant cells.</p> <p>20 Q It's fair to say you're going to focus on the</p> <p>21 adherent macrophages in giant cells in the</p> <p>22 Perry case?</p> <p>23 A Yes.</p> <p>24 Q Okay. What happens with the macrophages is</p> <p>25 -- do they get signaled to the site?</p>

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<p>1 A So the signaling is very complex and it's</p> <p>2 reviewed in Dr. Anderson -- and it's just</p> <p>3 part of the foreign body reaction. When you</p> <p>4 implant a foreign body, many different types</p> <p>5 of cells infiltrate that site of injury, and</p> <p>6 there are various chemical signaling factors</p> <p>7 that are involved. It's just very complex.</p> <p>8 Q Well, let's not go down that road. I was</p> <p>9 trying to get to a simplistic step-by-step</p> <p>10 process.</p> <p>11 So the macrophages are signaled to the</p> <p>12 site of the mesh or wherever there would be a</p> <p>13 foreign body?</p> <p>14 A I would say that monocytes are recruited due</p> <p>15 to the injury, and that mechanism is very</p> <p>16 complex. But they go to the site of injury,</p> <p>17 and they adhere to the foreign body.</p> <p>18 Q Okay. I guess the question I want to ask is,</p> <p>19 monocytes in the foreign body giant cells,</p> <p>20 it's correct that they can persist at the</p> <p>21 site of a foreign body for years, correct?</p> <p>22 A So Dr. Anderson teaches in that review that</p> <p>23 they're present --</p> <p>24 Q Can you answer my question yes or no and then</p> <p>25 the basis after?</p>	<p>1 Academy, and his seminal work is in this area</p> <p>2 of foreign body reaction. And in this paper,</p> <p>3 he is saying that the cells adhere and become</p> <p>4 activated. And I know that there is a fair</p> <p>5 amount of scientific research aimed at this</p> <p>6 idea of inactivating macrophages. I'm aware</p> <p>7 of this.</p> <p>8 But, again, to my knowledge, the teaching</p> <p>9 in the field is that they are activated. The</p> <p>10 work I've done with Dr. Iakovlev is saying</p> <p>11 that when we see these cells, we see</p> <p>12 myeloperoxidase when we stain for it. So</p> <p>13 that's why I'm expressing the opinion with a</p> <p>14 reasonable degree of scientific certainty</p> <p>15 that these cells are activated and secrete</p> <p>16 ROS when they are attached, when they adhere</p> <p>17 to the foreign body.</p> <p>18 Q Did you look for literature that was contrary</p> <p>19 to your opinion that these cells remain</p> <p>20 activated?</p> <p>21 A I'm aware of work in this area just through</p> <p>22 my work that I do. I can't think of a</p> <p>23 specific paper right now. If you have one</p> <p>24 you want me to look at, I can. I'm just</p> <p>25 expressing my general understanding in the</p>
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<p>1 A Okay. It's just the way you're phrasing it,</p> <p>2 I don't necessarily want to say yes or --</p> <p>3 that's the only problem.</p> <p>4 Q All right. Fair enough.</p> <p>5 A I want to answer. I just want to make sure</p> <p>6 that there is a clean record of what I'm</p> <p>7 saying.</p> <p>8 Q All right. So macrophages formed by giant</p> <p>9 cells can persist at the site of the mesh or</p> <p>10 foreign body; is that correct?</p> <p>11 A Yes, they are there -- again, in the Anderson</p> <p>12 paper, they are there for the lifetime of the</p> <p>13 device. They're persisting.</p> <p>14 Q And when you say the Anderson paper, is that</p> <p>15 the one you identified earlier on the record,</p> <p>16 sir?</p> <p>17 A Yes, sir.</p> <p>18 Q Okay. Thank you.</p> <p>19 Now, isn't it true, Doctor, that those</p> <p>20 macrophages in foreign body cells that</p> <p>21 persist at the site of the foreign body can</p> <p>22 become quiescent?</p> <p>23 A I've seen this idea proposed. Again, I'm</p> <p>24 relying on Dr. Anderson's 2008 review. And</p> <p>25 Dr. Anderson is a member of the National</p>	<p>1 field without any documents in front of me.</p> <p>2 Q You're aware of the belief in the field that</p> <p>3 these inflammatory cells can become</p> <p>4 quiescent, and they do not necessarily remain</p> <p>5 activated at the site of the foreign body?</p> <p>6 A I don't -- there are ideas that -- I don't</p> <p>7 know that -- quiescent I think is a strong</p> <p>8 word. Maybe there are varying levels of</p> <p>9 activity, but I don't know that I've seen</p> <p>10 convincing proof that they are just</p> <p>11 completely quiescent. Again, if you would</p> <p>12 like me to look at a paper, I will look at</p> <p>13 one, but this is my understanding.</p> <p>14 Q What are lysosomal constituents?</p> <p>15 A Can you put some context to that? I'm not</p> <p>16 -- just to give me a phrase. Lysosomal</p> <p>17 constituents, I mean, what's the context of</p> <p>18 it?</p> <p>19 Q With regard to foreign body giant cells,</p> <p>20 whether they remain activated releasing their</p> <p>21 lysosomal constituents?</p> <p>22 A I'm just not -- I could look at something.</p> <p>23 It's hard for me to answer that just in the</p> <p>24 way that question is phrased. I would have</p> <p>25 to look at what you're referring to, because</p>

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<p>1 I am just not sure what you mean.</p> <p>2 Q Did you research the question of whether</p> <p>3 inflammatory cells become quiescent or</p> <p>4 deactivated at the site of a foreign body?</p> <p>5 A I don't remember specifically doing that for</p> <p>6 this particular litigation.</p> <p>7 Q Are there any books in your field considered</p> <p>8 authoritative or important to these general</p> <p>9 principles of foreign body reaction?</p> <p>10 A I don't know. There is lots of -- I mean,</p> <p>11 I've got a book on biomaterials that has --</p> <p>12 Professor David Williams has just released a</p> <p>13 book on biomaterials. There is a book</p> <p>14 Biomaterials Science by four very well-known</p> <p>15 senior scientists that discuss these ideas.</p> <p>16 You know, these are all important books.</p> <p>17 Q Let me ask you this. Is there any way to</p> <p>18 test to know whether the cells are remaining</p> <p>19 activated?</p> <p>20 A Well, that's the myeloperoxidase stain. When</p> <p>21 I see a positive stain for MPO, that's</p> <p>22 staining for that enzyme, and that's telling</p> <p>23 us that the cells are generating ROS. That's</p> <p>24 how you do it.</p> <p>25 Q Is there any other test that you can do that</p>	<p>1 A I understand.</p> <p>2 Q In the paper by Jim Anderson, does he state</p> <p>3 that those macrophages in foreign body cells</p> <p>4 continue to release the substances at the</p> <p>5 site of the foreign body as years continue to</p> <p>6 progress and they remain activated? Is that</p> <p>7 conclusively stated in the paper?</p> <p>8 A So I'd like to answer that by stating what</p> <p>9 Dr. Anderson does say in that paper. He says</p> <p>10 that the cells become activated, and that the</p> <p>11 foreign body reaction is present throughout</p> <p>12 the lifetime of the device. And then he</p> <p>13 qualifies that as, albeit, in some cases at a</p> <p>14 low level.</p> <p>15 So what he is saying, and then what his</p> <p>16 point is, is that as long as the device is</p> <p>17 there, this foreign reaction body is ongoing,</p> <p>18 and that these factors need to be considered</p> <p>19 in the design of the medical device. That's</p> <p>20 what he says.</p> <p>21 Q Okay. So Dr. Anderson does not state that if</p> <p>22 the cells are there, they are going to be</p> <p>23 activated and producing these substances?</p> <p>24 A I would say it's implied. It doesn't</p> <p>25 necessarily specifically state that. And I</p>
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<p>1 would actually show those substances released</p> <p>2 by the ROS?</p> <p>3 A It's more difficult to do because they are</p> <p>4 such small molecules. The myeloperoxidase</p> <p>5 is just a very -- you know, it's a relatively</p> <p>6 straight forward stain to do.</p> <p>7 Q Do you know if the MPO stain is recognized by</p> <p>8 the American College of Pathology as a proper</p> <p>9 stain for assessing the release of that</p> <p>10 substance by ROS?</p> <p>11 A I don't know. We looked at -- you know, I</p> <p>12 published this, so it's been peer-reviewed.</p> <p>13 It was accepted as a marker of presence of</p> <p>14 oxidative conditions.</p> <p>15 Q Does Dr. Williams' paper that you referenced</p> <p>16 state with certainty that those macrophages</p> <p>17 of foreign body giant cells continue to</p> <p>18 remain activated and release substances on</p> <p>19 the surface of the biomaterial?</p> <p>20 A I think you're getting papers confused. I</p> <p>21 was referring to the Anderson 2008 paper.</p> <p>22 Q Okay. I'm sorry. So let me just ask a</p> <p>23 better question. Anytime you need to the</p> <p>24 correct me, let me know. I get these things</p> <p>25 confused.</p>	<p>1 would be happy to read it from the paper, but</p> <p>2 it's very strongly implied that that's what's</p> <p>3 happening in the way that it is stated.</p> <p>4 THE WITNESS: I have to go to</p> <p>5 the bathroom if you don't mind.</p> <p>6 MR. SNELL: Let's take a break.</p> <p>7 (A lunch recess is taken from</p> <p>8 12:00 to 12:50 p.m.)</p> <p>9 THE COURT: Let's take a break.</p> <p>10 BY MR. SNELL:</p> <p>11 Q Doctor, we are going to mark the Perry</p> <p>12 pathology slides that you have in your</p> <p>13 possession as Exhibit No. 2.</p> <p>14 (Deposition Exhibit No. 2 is</p> <p>15 marked for identification.)</p> <p>16 BY MR. SNELL:</p> <p>17 Q And I will hand you Exhibit 2. Just confirm</p> <p>18 for the record that those are the slides,</p> <p>19 sir.</p> <p>20 A Yes, these are the slides I was presented.</p> <p>21 Q It looks like there is three different sets,</p> <p>22 each of them wrapped in bubble wrap?</p> <p>23 A Yes.</p> <p>24 Q Am I correct, sir, that you're not relying on</p> <p>25 those pathology slides for your opinions?</p>

23 (Pages 86 to 89)

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<p>1 A That's correct.</p> <p>2 Q Do you know what type of inflammatory cells,</p> <p>3 if any, are present in Mrs. Perry's mesh?</p> <p>4 A I don't know. I didn't look at the slides</p> <p>5 under a microscope.</p> <p>6 Q You therefore would not know how many of any</p> <p>7 inflammatory cells, if they are present, were</p> <p>8 actually there, correct?</p> <p>9 A That's correct.</p> <p>10 Q When we were talking about the inflammatory</p> <p>11 cells, just so we're on the same page, I'm</p> <p>12 referring to the macrophages in foreign body</p> <p>13 giant cells?</p> <p>14 A Yes.</p> <p>15 Q Okay. So when we say chronic inflammatory</p> <p>16 cells --</p> <p>17 A Yes.</p> <p>18 Q -- are we talking about macrophages in the</p> <p>19 foreign body giant cells?</p> <p>20 A Yes.</p> <p>21 Q Okay. Do you know whether there were any</p> <p>22 chronic inflammatory cells present in</p> <p>23 Mrs. Perry's vaginal tissue before her</p> <p>24 surgeries, one of which included mesh?</p> <p>25 A I'm not aware of that information.</p>	<p>1 It's not going to work on a histological</p> <p>2 section. You would need mesh from the</p> <p>3 patient before it's been processed for</p> <p>4 histology to do those measurements.</p> <p>5 Q You said that was nano --</p> <p>6 A Nanoindentation could measure the brittleness</p> <p>7 of the surface degraded layer.</p> <p>8 Q Is that a particular type of test,</p> <p>9 nanoindentation?</p> <p>10 A It is.</p> <p>11 Q Is it separate and apart from some of the</p> <p>12 other testing that we've discussed?</p> <p>13 A It is. It is mechanical testing at a very</p> <p>14 small scale. I've done testing like this</p> <p>15 with a collaborator at Vanderbilt where we</p> <p>16 probed the surface with a cantilever beam,</p> <p>17 and we measure the response and the</p> <p>18 mechanical force. You can measure an elastic</p> <p>19 modulus doing this.</p> <p>20 Q You have not done any of this</p> <p>21 nanoindentation testing on Mrs. Perry's mesh,</p> <p>22 correct?</p> <p>23 A That's correct.</p> <p>24 Q Have you seen any photographs of Mrs. Perry's</p> <p>25 mesh that showed cracking?</p>
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<p>1 Q Did you attempt to look at any of the</p> <p>2 pathology reports in Mrs. Perry's case?</p> <p>3 A No, I did not review those reports.</p> <p>4 Q Have you attempted to measure any of the</p> <p>5 reactive oxygen species in Mrs. Perry?</p> <p>6 A We talked about this earlier. I didn't do</p> <p>7 that.</p> <p>8 Q Have you attempted to do any mechanical</p> <p>9 testing of Mrs. Perry's mesh?</p> <p>10 A No.</p> <p>11 Q Are you aware of any testing done on</p> <p>12 Mrs. Perry's mesh to determine whether it</p> <p>13 became tougher after implantation?</p> <p>14 A I'm not aware of any other testing on her</p> <p>15 mesh.</p> <p>16 Q And you would not have done such testing to</p> <p>17 determine whether it became tougher, correct?</p> <p>18 A Seems like -- I'm not sure what you mean by</p> <p>19 the mesh became tougher. I mean, it seems</p> <p>20 like it would be difficult to do.</p> <p>21 Q You could test to determine whether the mesh</p> <p>22 became embrittled in Mrs. Perry, correct?</p> <p>23 A Test the outer layer, that could be done by a</p> <p>24 nanoindentation. But, again, you need an</p> <p>25 appropriate amount of mesh in the right form.</p>	<p>1 A I've not seen any photographs of her mesh.</p> <p>2 Q Earlier you were talking about the bonding</p> <p>3 that can occur leading to degradation of the</p> <p>4 particular atom. I don't recall if it was</p> <p>5 carbon or hydrogen.</p> <p>6 A You are referring to oxidation and a free</p> <p>7 radical attack on a tertiary carbon hydrogen</p> <p>8 bond?</p> <p>9 Q Yes, sir.</p> <p>10 A Yeah.</p> <p>11 Q So for oxidation, is that oxygen which comes</p> <p>12 and bonds with carbon or the other way</p> <p>13 around?</p> <p>14 A The details of the reaction are very complex.</p> <p>15 But, essentially, it's a radical attack, a</p> <p>16 hydroxyl radical or oxygen radical can attack</p> <p>17 that bond. The chemistry is very</p> <p>18 complicated.</p> <p>19 Q What is the difference between an oxygen</p> <p>20 molecule and an oxygen radical?</p> <p>21 A Well, it's just the nature of the chemical</p> <p>22 reaction. In the body -- and in our in vitro</p> <p>23 testing -- I can speak specifically from our</p> <p>24 in vitro testing, the solution that we</p> <p>25 created generated hydroxyl radicals, and those</p>

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<p>1 hydroxl radicals attacked that carbon</p> <p>2 hydrogen tertiary bond -- tertiary carbon</p> <p>3 hydrogen bond.</p> <p>4 The hydroxl radicals attacked that bond,</p> <p>5 and that's where the pollen becomes oxidized.</p> <p>6 And then there is a number of steps in this</p> <p>7 reaction, I would have to look at a paper to</p> <p>8 explain it, but there is just a number of</p> <p>9 steps in that chemical reaction. It's very</p> <p>10 complex.</p> <p>11 Q When you say the hydroxl radicals attacked</p> <p>12 the bond, is that that tertiary bond you were</p> <p>13 referring to?</p> <p>14 A Yes. It extracts the -- I would have to look</p> <p>15 at the paper to show the exact mechanism, but</p> <p>16 that tertiary carbon hydrogen bond is</p> <p>17 vulnerable to an oxidative attack. But the</p> <p>18 physical chemistry of that reaction is,</p> <p>19 again, complex.</p> <p>20 Q Is it correct that you have not seen the</p> <p>21 presence of a hydroxl radical in Mrs. Perry's</p> <p>22 case?</p> <p>23 A Yeah. As we have discussed before, I have</p> <p>24 not done the myeloperoxidase staining or</p> <p>25 looking for a radical, which would be very</p>	<p>1 carbon-oxygen bonds that we can detect by</p> <p>2 XPS.</p> <p>3 Q Have you attempted to look for the presence</p> <p>4 of carbon-oxygen bond in Mrs. Perry's case?</p> <p>5 A I have not done that.</p> <p>6 Q Have you attempted to look for the percent of</p> <p>7 carbon in Mrs. Perry's mesh?</p> <p>8 A I have not done that.</p> <p>9 Q Have you attempted to look for the percent of</p> <p>10 oxygen in Mrs. Perry's mesh?</p> <p>11 A No.</p> <p>12 Q You earlier mentioned different biomaterial</p> <p>13 books, one of which was your own, I believe?</p> <p>14 A I edited a book, Introduction to Bond</p> <p>15 Materials. It's on my CV.</p> <p>16 Q What biomaterial books are used at</p> <p>17 Vanderbilt?</p> <p>18 A So the BME department -- I mean, chemical</p> <p>19 engineering department, the biomedical</p> <p>20 engineering department, teaches a course in</p> <p>21 biomaterials. I'm not sure what they're</p> <p>22 using now. In the past, they have used a</p> <p>23 book by Johnna Temenoff on biomaterials. I</p> <p>24 think they have made some changes to that</p> <p>25 course. I've never taught that course, so I</p>
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<p>1 difficult to do in her case. I have not done</p> <p>2 that.</p> <p>3 Q As I understand it, the presence of hydroxl</p> <p>4 groups on a surface would be indicative of</p> <p>5 oxidation?</p> <p>6 A It's the OH group forms in a hydroperoxide</p> <p>7 intermediate. There is a hydroperoxide that</p> <p>8 forms on the oxidized polypropylene, and we</p> <p>9 can see that peak by IR spectroscopy.</p> <p>10 Q Have you attempted to do any IR spectroscopy</p> <p>11 in Mrs. Perry's case?</p> <p>12 A No, I have not done that.</p> <p>13 Q As I understand it, there is testing that can</p> <p>14 be performed to try to assess atomic</p> <p>15 percents, such as the percent carbon, percent</p> <p>16 oxygen, and percent nitrogen; is that</p> <p>17 correct?</p> <p>18 A There is a method called x-ray photoelectron</p> <p>19 spectroscopy. We will call it XPS. XPS</p> <p>20 tells us what percentage of the carbon is</p> <p>21 bound to other atoms. So in pure</p> <p>22 polypropylene, all of the carbons should be</p> <p>23 bound. Either the hydrogen or carbon, it's a</p> <p>24 hydrocarbon. When polypropylene becomes</p> <p>25 oxidized, we see the formation of</p>	<p>1 don't know all the details.</p> <p>2 Q Is your book used in teaching biomaterials</p> <p>3 at Vanderbilt?</p> <p>4 A Not to my knowledge. But that book was</p> <p>5 written for a somewhat different purpose than</p> <p>6 for a teaching textbook.</p> <p>7 Q I think earlier you mentioned another book</p> <p>8 called Biomaterials Sciences, and it had a</p> <p>9 couple of different editors or authors?</p> <p>10 A So there were two well-known books. The</p> <p>11 older one is -- well, I think it's called</p> <p>12 Biomaterials Sciences. It was --</p> <p>13 maybe endorsed isn't the word, but the</p> <p>14 Society for Biomaterials endorses this book.</p> <p>15 Endorses may be a strong word. They</p> <p>16 recognize this book as being an important</p> <p>17 book, and there are four senior authors on</p> <p>18 this book.</p> <p>19 It's written more as a reference text.</p> <p>20 It's difficult to teach from, because it's an</p> <p>21 edited book. So it's an excellent resource</p> <p>22 for study. But for teaching undergraduates,</p> <p>23 it's not as accessible. So Professor David</p> <p>24 Williams, who is also a lead world expert in</p> <p>25 biomaterials, has written a new textbook. I</p>

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<p>1 contributed some figures to that textbook.</p> <p>2 And Professor Williams' textbook has been</p> <p>3 assessed by my colleagues in BME at</p> <p>4 Vanderbilt for teaching. I'm not sure if</p> <p>5 they've made a final decision whether to use</p> <p>6 it. What's attractive about that book for</p> <p>7 teaching is it's written by one author. So</p> <p>8 it's a single-author book, and so this is</p> <p>9 good for teaching undergraduates.</p> <p>10 My textbook, I edited, so there are</p> <p>11 chapters by individual contributors. So it's</p> <p>12 just a different book.</p> <p>13 Q When you were going about compiling your</p> <p>14 book, did you reach out to people who you</p> <p>15 felt were experts in certain fields to write</p> <p>16 or contribute to particular chapters?</p> <p>17 A That's how we approached editing the book,</p> <p>18 that's right. That was in 2005 when I was a</p> <p>19 postdoc.</p> <p>20 Q What is the most recent edition of your book?</p> <p>21 Is it on your CV?</p> <p>22 A Well, I co-edited the first edition. There</p> <p>23 is a second edition, but I didn't co-edit</p> <p>24 that one. The only one that I have co-edited</p> <p>25 has been published in 2006. It's on my CV.</p>	<p>1 Abbrevio?</p> <p>2 A I have not.</p> <p>3 Q Have you done any testing of any type on TVT</p> <p>4 product for stress incontinence? And when I</p> <p>5 stay TVT, I mean Ethicon's particular TVT</p> <p>6 product.</p> <p>7 A So only the testing performed at Dr. Dunn's</p> <p>8 laboratory. Just to be clear, Dr. Dunn did</p> <p>9 that testing. I consulted and advised. We</p> <p>10 discussed it, agreed to do it, but Dr. Dunn</p> <p>11 physically performed the testing.</p> <p>12 Q Tell me what testing did Dr. Dunn do on an</p> <p>13 Ethicon TVT device. As I had read -- and</p> <p>14 I'll tell you why I'm asking. As I had read</p> <p>15 your Huskey deposition testimony, he had done</p> <p>16 some testing on maybe one or more AMS meshes</p> <p>17 and Boston Scientific meshes.</p> <p>18 A These are new testing that we've done.</p> <p>19 Q Let me just back up then. So as I understand</p> <p>20 it, Dr. Dunn has done some testing on Ethicon</p> <p>21 TVT products?</p> <p>22 A Yes.</p> <p>23 Q Are you relying on that testing for your</p> <p>24 opinions in the Perry case?</p> <p>25 A Let me look at my opinions for a minute.</p>
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<p>1 Q The Society for Biomaterials, you referenced</p> <p>2 you're a member of that society?</p> <p>3 A I am.</p> <p>4 Q And the book they recognize as being an</p> <p>5 important book is Biomaterials Sciences. Is</p> <p>6 the title An Introduction to Materials and</p> <p>7 Medicine by --</p> <p>8 A That sounds right.</p> <p>9 Q -- Buddy Ratner?</p> <p>10 A Buddy Ratner, Hoffman, Schoen. They're all</p> <p>11 founders of the Society for Biomaterials,</p> <p>12 very well-known. Jack Lemons is the other</p> <p>13 author.</p> <p>14 Q Did any of those authors contribute to your</p> <p>15 book?</p> <p>16 A I don't remember. I don't think so.</p> <p>17 Q I want to ask you some questions about TVT</p> <p>18 Abbrevio. I'm just trying to give you an idea</p> <p>19 of where I'm going.</p> <p>20 A Okay.</p> <p>21 Q Because I know we went back and kind of</p> <p>22 covered some things that we addressed earlier</p> <p>23 with further questions.</p> <p>24 A Okay.</p> <p>25 Q Have you done any testing of any type on TVT</p>	<p>1 Yes, I am relying on that testing. So I</p> <p>2 should say, I formed my opinions based on the</p> <p>3 literature review. My opinions are the same</p> <p>4 as they were in the Huskey case on this</p> <p>5 particular topic of oxidation and</p> <p>6 degradation, and this testing further</p> <p>7 confirms my opinions.</p> <p>8 And the testing was specifically done to</p> <p>9 answer the question that Ethicon raised</p> <p>10 during the trial in August, that Prolene is</p> <p>11 different from polypropylene and doesn't</p> <p>12 oxidize because it has antioxidants.</p> <p>13 So in the testing done by Dr. Dunn, the</p> <p>14 goal was to answer the question can Prolene</p> <p>15 in a TVT device oxidize and degrade. And we</p> <p>16 saw oxidation and degradation of the surface</p> <p>17 pitting in that testing, in the oxidative</p> <p>18 medium that I was describing earlier. So the</p> <p>19 testing was performed to answer a very</p> <p>20 specific question of -- and to answer the</p> <p>21 specific question of can the Prolene</p> <p>22 polypropylene oxidize. That was the purpose</p> <p>23 of the test.</p> <p>24 Q Where is this testing, all of the notebooks,</p> <p>25 the results, the data generated from it that</p>

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<p>1 you are relying on?</p> <p>2 A So this is on the disk that was provided.</p> <p>3 Q Okay. Show me where on the disk that that is</p> <p>4 this TVTG testing is located.</p> <p>5 A I don't have a computer but --</p> <p>6 Q Can you use Mr. Kuntz'?</p> <p>7 MR. KUNTZ: He can.</p> <p>8 Let's go off the record for a second.</p> <p>9 (Off-the-record discussion.)</p> <p>10 BY MR. SNELL:</p> <p>11 Q Counsel is looking at the thumb drive.</p> <p>12 Obviously, I can't look at it and question</p> <p>13 the witness about 6,000 files today. Let me</p> <p>14 just get some basic information about this</p> <p>15 testing.</p> <p>16 The testing that was performed on</p> <p>17 Ethicon's TVT mesh, what specific device or</p> <p>18 devices were the subject of the testing?</p> <p>19 A I believe it was the TVT.</p> <p>20 Q The original TVT retropubic?</p> <p>21 A I believe so. And we also tested an</p> <p>22 unstabilized polypropylene controlled, it had</p> <p>23 no antioxidant.</p> <p>24 Q Okay. You said it was an unstabilized</p> <p>25 Prolene polypropylene?</p>	<p>1 A I am just disclosing what we did.</p> <p>2 Q This TVT retropubic device that Dr. Dunn</p> <p>3 tested, was it one single device or was it a</p> <p>4 batch or numerous ones?</p> <p>5 A I believe it was one device with three</p> <p>6 replicate pieces, three distinct pieces cut</p> <p>7 from -- it was three or four. I can't</p> <p>8 remember the details. I would have to look</p> <p>9 at it. But there were multiple replicates</p> <p>10 cut from the same mesh.</p> <p>11 Q And the unstabilized polypropylene control,</p> <p>12 where was that obtained from?</p> <p>13 A I would have to look at the document to look</p> <p>14 at the documents for the exact source, but it</p> <p>15 was purchased from a third-party vendor that</p> <p>16 sells polypropylene with antioxidants,</p> <p>17 unstabilized polypropylene.</p> <p>18 Q Do you know the vendor?</p> <p>19 A I can't remember. It's in the documents. I</p> <p>20 would have to find it.</p> <p>21 Q Do you know who purchased this control?</p> <p>22 A Dr. Dunn purchased it and did all of this</p> <p>23 work.</p> <p>24 Q You personally were not the one who did any</p> <p>25 of this testing on the TVT retropubic device,</p>
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<p>1 A No. It's polypropylene without antioxidants.</p> <p>2 So it would be the equivalent of -- in the</p> <p>3 Liebert paper where they tested the</p> <p>4 monofilament with no stabilizers. It's a</p> <p>5 polypropylene that has no antioxidants. So</p> <p>6 it's unstabilized polypropylene I would call</p> <p>7 it.</p> <p>8 Q So you didn't test the TVT retropubic mesh</p> <p>9 with antioxidants to the TVT retropubic mesh</p> <p>10 with antioxidants?</p> <p>11 A No, we can't get TVT without the -- the TVT</p> <p>12 is made from Prolene that has that Prolene</p> <p>13 antioxidant package, because that's what we</p> <p>14 tested, that's what we could get. So we had</p> <p>15 that exemplar, Dr. Dunn had it, and we</p> <p>16 compared that to the unstabilized</p> <p>17 polypropylene. We also tested two Boston</p> <p>18 Scientific meshes, but that's not in the</p> <p>19 materials that we presented. That's</p> <p>20 different.</p> <p>21 Q You are not relying on this Boston Scientific</p> <p>22 testing for your opinions in this matter,</p> <p>23 correct?</p> <p>24 A I am not.</p> <p>25 Q Okay.</p>	<p>1 correct?</p> <p>2 A No. As I said previously, Dr. Dunn and I</p> <p>3 consulted, and Dr. Dunn did all of the work</p> <p>4 physically through his company.</p> <p>5 Q So am I correct that you did not do any of</p> <p>6 the physical testing of this TVT or the</p> <p>7 control?</p> <p>8 A That's right. Dr. Dunn did.</p> <p>9 Q And that was done at his company?</p> <p>10 A Yes.</p> <p>11 Q Was that testing done out of his house?</p> <p>12 A I don't know. Maybe some of it was done from</p> <p>13 his house. I don't remember.</p> <p>14 Q Do you know where the testing took place on</p> <p>15 this TVT retropubic compared to the</p> <p>16 polypropylene control?</p> <p>17 A It was done in his lab at Vanderbilt.</p> <p>18 Q Who paid for the testing that Dr. Dunn</p> <p>19 performed comparing the TVT retropubic to the</p> <p>20 unstabilized polypropylene control?</p> <p>21 A I should clarify that all of these responses</p> <p>22 I'm telling you to the best of my knowledge.</p> <p>23 And if Dr. Dunn contradicts what I'm saying,</p> <p>24 it's because I didn't remember it correctly.</p> <p>25 I believe that this testing was billed to the</p>

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<p>1 litigation, but Dr. Dunn would have to</p> <p>2 confirm that.</p> <p>3 Q Is your basis for your testimony in that</p> <p>4 regard something that Dr. Dunn told you?</p> <p>5 A Yes, I'm basing it on -- I have not seen</p> <p>6 those invoices. That would be between</p> <p>7 Dr. Dunn and plaintiff's counsel.</p> <p>8 Q Did Dr. Dunn physically do all of his</p> <p>9 testing?</p> <p>10 A Again, I believe that he did, but I don't</p> <p>11 know the details of -- he would be the one</p> <p>12 that would have to speak to that.</p> <p>13 Q Unfortunately, he is not identified as an</p> <p>14 expert here.</p> <p>15 A I understand that.</p> <p>16 Q Were you present for any of the physical</p> <p>17 testing of the TVT retropubic or the</p> <p>18 unstabilized polypropylene control?</p> <p>19 A Was I present?</p> <p>20 Q Present meaning on the premises where the</p> <p>21 testing was performed, such that you could</p> <p>22 yourself observe the testing.</p> <p>23 A Well, the testing was just very simple.</p> <p>24 Dr. Dunn placed the -- I'm trying to answer</p> <p>25 your question as best I can. So Dr. Dunn</p>	<p>1 A Same time frame. Maybe August -- it would</p> <p>2 have been September of 2014 after the Huskey</p> <p>3 trial. And, again, the motivation for the</p> <p>4 tests was based on Ethicon's statements</p> <p>5 during trial that we had not tested it and</p> <p>6 couldn't -- we could not say definitively</p> <p>7 that Prolene polypropylene oxidizes, and that</p> <p>8 was the motivation for the test.</p> <p>9 So this is what was said in Huskey trial,</p> <p>10 we decided to do the test to answer that</p> <p>11 specific question, can Prolene polypropylene</p> <p>12 oxidize.</p> <p>13 Q Now, Dr. Dunn's Vanderbilt lab, is that on</p> <p>14 the premises here at Vanderbilt?</p> <p>15 A Yes, his lab is at Vanderbilt.</p> <p>16 Q Do you know if any graduate students or</p> <p>17 other people were involved in the testing?</p> <p>18 A Dr. Dunn has employees. I know that. To</p> <p>19 what extent they were involved in the</p> <p>20 testing, I can't speak to. Again, Dr. Dunn</p> <p>21 just did all of his. I don't know those</p> <p>22 details.</p> <p>23 I should qualify my comment. Dr. Dunn</p> <p>24 does not have employees, but I know that he</p> <p>25 does pay contractors for services like he</p>
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<p>1 placed the specimens in vials. They were</p> <p>2 weighted down with glass beads in this</p> <p>3 oxidative medium that I was describing that</p> <p>4 simulates the environment between the</p> <p>5 adherent inflammatory cells and the</p> <p>6 biomaterial. I have seen those vials.</p> <p>7 And then at different time points,</p> <p>8 Dr. Dunn removed the test specimens, rinsed</p> <p>9 and dried them, and measured RI spectra. And</p> <p>10 I've seen those dried specimens. I've seen</p> <p>11 the specimens, and so I have seen aspects of</p> <p>12 the testing, but I didn't watch him do the</p> <p>13 testing. But the testing essentially</p> <p>14 involves incubating the material in a</p> <p>15 solution, and then taking it out and testing</p> <p>16 it by FTIR and SEM.</p> <p>17 Q When was this testing on the TVT retropubic</p> <p>18 device done?</p> <p>19 A September and October of 2014.</p> <p>20 Q And it was on a single TVT retropubic</p> <p>21 exemplar, meaning that mesh had not been in</p> <p>22 the body at all?</p> <p>23 A That's correct.</p> <p>24 Q When did you first discuss with Dr. Dunn this</p> <p>25 testing on the TVT retropubic exemplar?</p>	<p>1 pays me. But, again, I cannot speak to how</p> <p>2 he conducts his business.</p> <p>3 Q Why did Dr. Dunn choose to test only one TVT</p> <p>4 retropubic device?</p> <p>5 A That was what we had at the time. And we</p> <p>6 knew these depositions and report deadlines</p> <p>7 were approaching quickly, so we moved forward</p> <p>8 with what we had.</p> <p>9 Q Would you have preferred to have more than</p> <p>10 one TVT retropubic to test?</p> <p>11 A We requested additional exemplars from</p> <p>12 plaintiff's counsel. My understanding is</p> <p>13 that this is a complex request and takes</p> <p>14 time. We have requested additional items</p> <p>15 recognizing the need to test multiple</p> <p>16 meshes. But as I said, these requests can</p> <p>17 take time to process, so we tested what we</p> <p>18 had.</p> <p>19 Q Why is there a need to test multiple meshes?</p> <p>20 A I should qualify my answer I need to test.</p> <p>21 By testing multiple products, it's possible</p> <p>22 to show that it would happen in many of these</p> <p>23 products. It's not possible to test every</p> <p>24 one. But considering that the oxidation of</p> <p>25 polypropylene is due to the inherent</p>

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<p>1 intrinsic molecular structure of 2 polypropylene, as well as the antioxidant 3 package, if those things are all the same, 4 you would expect a very similar response. 5 Like I said, it's a chemical reaction. 6 So if it's the same material with the same 7 antioxidants, you would expect to see a very 8 similar chemical reaction. We tested two 9 Boston Scientific meshes because we had to. 10 If we had had more, we could have tested more 11 and would have liked to have done that, but 12 we were limited to what we had at the time. 13 MR. SNELL: I'm going to move to 14 strike the part about Boston Scientific. 15 A I understand. I shouldn't have said that. 16 I'm sorry. 17 BY MR. SNELL: 18 Q So you would expect to see a similar response 19 you said, correct? 20 A Yes. 21 Q If you tested multiple meshes, correct? 22 A I would. 23 Q But we know from the teachings of Clave that 24 not all findings will be consistent with 25 regard to degradation, correct?</p>	<p>1 Journal of Biomedical Materials Research. In 2 the 1990 paper is a seminal paper where 3 Dr. Anderson discovered the effects of the 4 foreign body reaction on a biomedical device. 5 The 1993 paper he simulated. He 6 reproduced or recapitulated that same 7 oxidation and degradation in that same 8 biomaterial in vitro outside the body. So he 9 was able to show that this solution, this 10 oxidative solution that I've been talking 11 about recapitulates the oxidative conditions 12 that the biomaterial was exposed to in vitro. 13 I should qualify my previous comment when 14 I said there is no cells. There is no other 15 cell populations like fibroblasts that are 16 exerting contractile forces. There is no 17 tissue that is exerting forces. So this test 18 is isolating the effects of chemical 19 oxidation and was found to agree with in vivo 20 observations. That's the purpose of the 21 test, and those two papers have shown that. 22 So I hope I'm answering your question. 23 It reproduces certain aspects of the 24 reaction, but not every -- but the ones that 25 I just mentioned.</p>
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<p>1 MR. KUNTZ: Objection. 2 A I think that the conditions are very 3 different. Clave is in vivo explant, so 4 there are many different factors affecting 5 oxidation. This study was purely isolating 6 the chemical reaction. The medium that we 7 used has been published by a number of 8 investigators, including me, that simulates 9 the oxidative conditions in the body. 10 So we're simulating a chemical reaction, 11 not -- there is no cells. There is no 12 tissue. It is simply examining that chemical 13 reaction, will that chemical reaction cause a 14 change in Prolene polypropylene. That was 15 the purpose of the test, so it's very 16 different from, say, Clave's study. It is 17 very specific. 18 That is why I would expect to see the 19 same changes in any mesh that we tested. 20 BY MR. SNELL: 21 Q So this study done in a lab is not under the 22 same conditions as one would see in vivo? 23 A I wouldn't -- I would qualify that -- there 24 are two papers in my reliance materials by 25 Dr. Jim Anderson from 1990 and 1993 in the</p>	<p>1 Q The test that was done on the TVT device does 2 not establish that an oxidative condition 3 occurs in vivo; is that correct? 4 MR. KUNTZ: Objection. 5 A Let me -- the in vitro test does not 6 establish the in vivo conditions. It's 7 recapitulating those in vivo conditions. We 8 know that this happens in the foreign body 9 reaction, and so the test is designed to 10 recapitulate that foreign body reaction in 11 the laboratory. 12 Q What are the limitations to the test as it 13 was conducted by Dr. Dunn utilizing only one 14 TVT device? 15 A Well, the limitation of the test is -- I want 16 to be very careful about my opinion. The 17 question we were asking was -- and what I was 18 presented with in trial, and I believe what 19 Dr. Shelby Thames testified for defense was 20 Prolene polypropylene doesn't oxidize. It's 21 stabilized. It's different. It's Prolene. 22 So we asked a very simple question, can 23 Prolene polypropylene oxidize. 24 We tested one mesh. And we showed that 25 in that one mesh that we tested, Prolene</p>

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<p>1 polypropylene oxidized. We have also showed</p> <p>2 evidence of pitting and surface degradation.</p> <p>3 So the limitation would be, we're not saying</p> <p>4 that we saw it in every mesh, we're not</p> <p>5 saying we saw it in 10,000 meshes. We're</p> <p>6 saying we saw it in one mesh. And we</p> <p>7 answered this question that it can oxidize.</p> <p>8 Because it's a chemical reaction, I believe</p> <p>9 we would see it in other meshes if we tested</p> <p>10 those, but I recognize that we didn't. We</p> <p>11 tested one mesh, but we did show that it can</p> <p>12 happen in that one mesh.</p> <p>13 Q So with that said, let's go back to my</p> <p>14 question. What are the limitations of the</p> <p>15 testing that Dr. Dunn did given there was</p> <p>16 only one TVT mesh?</p> <p>17 MR. KUNTZ: Objection, asked and</p> <p>18 answered.</p> <p>19 A I thought I answered it. I will try a</p> <p>20 briefer answer. The limitation would be that</p> <p>21 we tested one mesh. We showed that it can</p> <p>22 happen. We did not estimate a probability</p> <p>23 that it would happen. We tested one mesh and</p> <p>24 saw that it happened in that mesh that we</p> <p>25 tested.</p>	<p>1 events.</p> <p>2 It starts to oxidize immediately when</p> <p>3 it's implanted. It's colonized by</p> <p>4 macrophages. I believe with a reasonable</p> <p>5 degree of scientific certainty it will start</p> <p>6 to oxidize upon implantation. When it</p> <p>7 becomes induced, and there are much more</p> <p>8 dramatic changes in physical properties is</p> <p>9 unpredictable, as I've said in previous</p> <p>10 testimony. Those events are unpredictable.</p> <p>11 But I do believe that the test tells us</p> <p>12 that the mesh can oxidize, and I would expect</p> <p>13 it to oxidize under in vivo conditions due to</p> <p>14 the nature of the inflammatory response that</p> <p>15 we discussed.</p> <p>16 MR. SNELL: Move to strike.</p> <p>17 BY MR. SNELL:</p> <p>18 Q One of the limitations to the test that</p> <p>19 Dr. Dunn did on the single TVT retropubic</p> <p>20 device was that it does not establish that</p> <p>21 Prolene polypropylene degrades in vivo; is</p> <p>22 that correct?</p> <p>23 A It does not establish? I'm having a hard</p> <p>24 time with this word establish. It supports</p> <p>25 my opinions that these meshes are -- can</p>
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<p>1 I believe the literature teaches with a</p> <p>2 reasonable degree of scientific certainty</p> <p>3 that it would happen in other meshes because</p> <p>4 presumably they are chemically the same. I</p> <p>5 didn't look at necessarily the manufacturing</p> <p>6 doc, but I would presume based on my industry</p> <p>7 experience that there are specifications for</p> <p>8 antioxidants and Prolene. I've seen some</p> <p>9 documents showings those numbers. Provided</p> <p>10 those compositions are the same, I would</p> <p>11 expect to see a very similar result, because</p> <p>12 it is a chemical test testing the effects of</p> <p>13 a specific chemical reaction.</p> <p>14 BY MR. SNELL:</p> <p>15 Q Is it fair to say that one of the limitations</p> <p>16 with that test is that it does not establish</p> <p>17 that Prolene polypropylene degrades in vivo?</p> <p>18 MR. KUNTZ: Objection.</p> <p>19 A I would say it doesn't establish the timing</p> <p>20 in which Prolene polypropylene oxidizes in</p> <p>21 vivo. The time scale at which this happens</p> <p>22 would depend on many other factors, the</p> <p>23 environment, the patient, I understand that,</p> <p>24 but I do believe that it shows that it would</p> <p>25 oxidize. It's just the timing of those</p>	<p>1 oxidize and degrade in vivo.</p> <p>2 Q I'm not asking you whether your</p> <p>3 interpretation as to whether it supports your</p> <p>4 opinion.</p> <p>5 MR. SNELL: So I would</p> <p>6 respectfully move to strike.</p> <p>7 BY MR. SNELL:</p> <p>8 Q The limitation to this test that Dr. Dunn did</p> <p>9 on the single TVT is that it does not</p> <p>10 establish that Prolene polypropylene degrades</p> <p>11 in vivo; is that correct?</p> <p>12 MR. KUNTZ: Objection. He said</p> <p>13 the exact same opposite.</p> <p>14 A I'm struggling with the way you phrased the</p> <p>15 question. I don't want to agree to that. I</p> <p>16 believe with a reasonable degree of</p> <p>17 scientific certainty that this test predicts</p> <p>18 susceptibility to oxidative degradation. And</p> <p>19 if we see it in vitro, we will see it in</p> <p>20 vivo.</p> <p>21 It's just the timing and the severity are</p> <p>22 unpredictable, but I do believe it will</p> <p>23 happen. I think that it's -- the timing and</p> <p>24 the severity, the clinical consequences are</p> <p>25 unpredictable. That's what I've been saying.</p>

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<p>1 MR. SNELL: Well, I respectfully</p> <p>2 move to strike again.</p> <p>3 BY MR. SNELL:</p> <p>4 Q Again, I'm not asking you about</p> <p>5 susceptibility to oxidation, and I'm not</p> <p>6 asking you about oxidation, that particular</p> <p>7 step. I'm asking you about degradation in</p> <p>8 vivo.</p> <p>9 So the question again. One of the</p> <p>10 limitations to those tests by Dr. Dunn on the</p> <p>11 single TVT is that it does not establish that</p> <p>12 Prolene polypropylene degrades in vivo; is</p> <p>13 that a fair statement?</p> <p>14 MR. KUNTZ: Objection.</p> <p>15 A You're speaking specifically of degradation?</p> <p>16 BY MR. SNELL:</p> <p>17 Q Yes, sir. That's why my question only said</p> <p>18 degradation.</p> <p>19 A Okay. I would like to explain my answer on</p> <p>20 this.</p> <p>21 Q Can you first agree or disagree and then</p> <p>22 please feel free to explain?</p> <p>23 A So you're saying that it does not establish</p> <p>24 that it degrades --</p> <p>25 Q I will ask it one more time.</p>	<p>1 performed; is that correct?</p> <p>2 A You're misunderstanding the purpose of the</p> <p>3 test.</p> <p>4 Q Sir, you have to listen to my questions and</p> <p>5 answer them yes or no or whatever. I'm not</p> <p>6 asking you about the purpose of the test and</p> <p>7 all of that.</p> <p>8 A That cannot be answered by a yes or no</p> <p>9 question. The macrophage is not there, but</p> <p>10 the consequence of the macrophage is there.</p> <p>11 That's the test.</p> <p>12 MR. SNELL: Move to strike.</p> <p>13 BY MR. SNELL:</p> <p>14 Q What macrophage --</p> <p>15 A I'm not going down on this. Go ahead. I'm</p> <p>16 sorry.</p> <p>17 Q Were macrophages present in the test that</p> <p>18 Dr. Dunn did on the single TVT retropublic?</p> <p>19 A Macrophages were not present, but what</p> <p>20 macrophages produce, meaning radicals and</p> <p>21 reactive oxygen was present. We generated</p> <p>22 those reactive species using a chemical</p> <p>23 reaction instead of a macrophage, but this is</p> <p>24 an acceptable accepted approach to doing</p> <p>25 that.</p>
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<p>1 A I'm trying to give you an accurate answer,</p> <p>2 and I'm struggling with how to answer this.</p> <p>3 Q One of the limitations to the test that</p> <p>4 Dr. Dunn performed on this single TVT</p> <p>5 retropublic device was that it does not</p> <p>6 establish that Prolene polypropylene degrades</p> <p>7 in vivo; is that a fair statement?</p> <p>8 MR. KUNTZ: Objection.</p> <p>9 A I just don't know if I can agree to that. I</p> <p>10 believe it -- it -- we didn't see -- I'm just</p> <p>11 having a hard time with this sentence. The</p> <p>12 way you phrase it, I would need to move on,</p> <p>13 so I will leave this for the attorneys later.</p> <p>14 But the way you are phrasing that question,</p> <p>15 for now I will agree to it. But I have</p> <p>16 reservations, because I don't believe it</p> <p>17 captures what I'm really testifying about.</p> <p>18 BY MR. SNELL:</p> <p>19 Q It is a simple fact, isn't it, Doctor, that</p> <p>20 this test that Dr. Dunn performed on the</p> <p>21 single TVT device, it is not an in vivo test?</p> <p>22 Can we agree to that?</p> <p>23 A I will agree that it is not an in vivo test.</p> <p>24 Q There were no macrophages put on the TVT</p> <p>25 retropublic device and this test that Dr. Dunn</p>	<p>1 Just because a macrophage was not there</p> <p>2 doesn't mean -- it's the same oxidative</p> <p>3 conditions. It's just accomplished through a</p> <p>4 different chemical reaction.</p> <p>5 MR. SNELL: Move to strike</p> <p>6 everything after macrophage was not present.</p> <p>7 A I'm not going to back down. We can stay here</p> <p>8 'til 5:00 arguing about this. I'm not going</p> <p>9 to back down the test.</p> <p>10 BY MR. SNELL:</p> <p>11 Q Sir, we are going to be here multiple days.</p> <p>12 I can tell you that now.</p> <p>13 A Fine. But I'm not -- you're trying to put</p> <p>14 words in my mouth.</p> <p>15 Q No, sir.</p> <p>16 MR. KUNTZ: We're not going to</p> <p>17 be here multiple days. We'll get your seven</p> <p>18 hours and we'll stay here as late as we can.</p> <p>19 So --</p> <p>20 MR. SNELL: No. First of all,</p> <p>21 you produced 6,000 pages.</p> <p>22 MR. KUNTZ: It doesn't matter.</p> <p>23 That's the rules under California. We have</p> <p>24 no obligation to produce at the start of his</p> <p>25 depo materials he relied on. There is no</p>

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<p>1 obligation under California state law to do 2 that. We have complied. We have brought a 3 disk and brought the materials responsive to 4 the deposition. That is the only thing that 5 is required under California law. I want to 6 make this clear. We have no duty to produce 7 before the depo anything, zero. 8 MR. SNELL: That's fine, if 9 that's your position. 10 MR. KUNTZ: Okay. 11 BY MR. SNELL: 12 Q Am I correct, sir, that there were no foreign 13 body giant cells that were used in Dr. Dunn's 14 test? 15 A My answer is the same. The cells weren't 16 there, but the reaction products were. 17 MR. SNELL: Move to strike after 18 the cells were not there. 19 A These are unreasonable questions. And this 20 deposition is going to get more hostile if 21 you keep going down this line of questioning, 22 just to put it out there. 23 Q Sir, as the witness, I'm allowed to ask you 24 questions. You may not like the question, 25 but you have to answer the questions.</p>	<p>1 is it that you believe this test on this 2 single TVT device compared to the control 3 shows? 4 A I believe that it shows Prolene polypropylene 5 used to manufacture the TVT device can 6 oxidize and degrade under oxidative 7 conditions similar to those experienced in 8 the human body after implantation. 9 Q What documents or files out of those 6,000 10 plus show the oxidation? 11 A The oxidation is evidenced by FTIRs spectra 12 that were measured in weeks zero, one, two, 13 three, four and five. In the FTIRs spectra, 14 we saw minimal hydroxyl and carbonyl peaks 15 until week five, where we saw a significant 16 increase in the magnitude of the hydroxyl 17 and/or carbonyl peaks, which was indicative 18 of a chemical induction. 19 Q So what are the file names and the documents 20 that showed this out of the 6,000? 21 A I don't remember the file names. 22 Q Well, I'm entitled to know them. 23 A I know. And I have to look at it. I don't 24 have it here with me. I know that you're 25 entitled to have it, but I don't have it here</p>
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<p>1 A But the questions are being phrased that 2 you're trying to misrepresent my testimony 3 and misrepresent what I'm saying. 4 Q I'm not trying to misrepresent your 5 testimony. 6 A You are. 7 Q I'm asking you a factual question. 8 A And the question is -- 9 Q Was there a horse in the room at the time of 10 the test, yes or no? No. 11 Was there a macrophage in the test, yes 12 or no? 13 The interpretation, I will get to that, 14 but I have simple questions, sir, and I'm 15 entitled to simple answers if they're simple 16 questions. You can talk to Mr. Kuntz all 17 night long about your interpretation. That's 18 fine. But I'm actually going to ask you 19 about your interpretation too. 20 A And I'm entitled to answer questions as I 21 need to. And I'm not going to be put into 22 this difficult position of having things 23 recorded as my testimony that's not what I've 24 ever been saying. 25 Q You would agree that -- let me back up. What</p>	<p>1 in front of me. 2 MR. KUNTZ: He does have it. 3 MR. SNELL: Out of the 6,000, 4 you think I am some kind of scientist and can 5 pick out this FTIR testing? 6 MR. KUNTZ: The rules are the 7 rules, Burt. You gave us testing two weeks 8 before trial. I don't cry about it. We 9 follow the rules. 10 MR. SNELL: All I'm asking him 11 is to identify it. 12 MR. KUNTZ: That's fine. We'll 13 sit here and he can identify it. Let's pull 14 it up. 15 MR. SNELL: That's what I 16 thought we were doing. 17 MR. KUNTZ: If that's how you 18 want to spend your seven hours with him, 19 let's do it. 20 MR. BOWMAN: There is a folder 21 named FTIR on the drive that was given to 22 you. It's already been disassembled and 23 separated out. There's FTIR, and there's 24 SEM, and XPS. 25 MR. KUNTZ: I'm trying to get</p>

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<p>1 you a link, so you can pull them up.</p> <p>2 BY MR. SNELL:</p> <p>3 Q What documents, if any, in this study that</p> <p>4 Dr. Dunn did on the single TVT device show</p> <p>5 that the Prolene polypropylene degrades?</p> <p>6 A There are SEM images at weeks zero and five,</p> <p>7 I believe. What the name of that file is, I</p> <p>8 don't know. I will have to look at the</p> <p>9 folders to try to find it.</p> <p>10 Q Okay. And what is it about those SEM images</p> <p>11 that you believe shows degradation?</p> <p>12 A There are changes in the surface, including</p> <p>13 pitting, flaking, changes to the surface that</p> <p>14 can be observed by SEM.</p> <p>15 Q How deep is the pitting?</p> <p>16 A I don't know. I would have to look at the</p> <p>17 image again to see it.</p> <p>18 Q How much material is flaking off?</p> <p>19 A Again, I would have to look at it to see</p> <p>20 that. We saw SEM is -- we were just really</p> <p>21 looking to see if it's there or not. It's</p> <p>22 difficult to be more quantitative as we can</p> <p>23 be with the FTIR, but we saw evidence of</p> <p>24 changes to the surface.</p> <p>25 Q Did you attempt to quantify the pitting?</p>	<p>1 the time point at which we did XPS. It's in</p> <p>2 the data. I just can't remember it.</p> <p>3 Q What, if anything, did the XPS show?</p> <p>4 A The XPS revealed the evidence of</p> <p>5 carbon-oxygen bonds on the surface of the</p> <p>6 TVT.</p> <p>7 Q How many carbon-oxygen bonds were seen?</p> <p>8 A So XPS, we did three distinct measurements at</p> <p>9 three surfaces on the fiber. We cannot see</p> <p>10 microscopically where we're testing, so it's</p> <p>11 not possible to tell whether we're testing</p> <p>12 where there is an area of active degradation</p> <p>13 or not. Does that make sense?</p> <p>14 There is areas of pitting on the fibers,</p> <p>15 and then there is areas on the fibers that we</p> <p>16 don't see the pitting. When we do the XPS</p> <p>17 measurements, we're not exactly sure of where</p> <p>18 on the fiber we're probing. We actually</p> <p>19 picked three spots. And the XPS measurement</p> <p>20 tells us at that particular spot that is</p> <p>21 being probed, what the percentage of the</p> <p>22 carbon is bound to oxygen. And we saw many</p> <p>23 spots. It's in the data. I just can't</p> <p>24 remember the exact numbers, but we saw many</p> <p>25 spots on the surface where we saw the</p>
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<p>1 A We were working on it. In the amount of time</p> <p>2 we had to pull this together, we haven't had</p> <p>3 time to do it yet.</p> <p>4 Q You attempted to quantify the amount of</p> <p>5 flaking?</p> <p>6 A Same answer.</p> <p>7 Q Not yet?</p> <p>8 A Not yet.</p> <p>9 Q Is there anything else about this test that</p> <p>10 Dr. Dunn did on the single TVT device?</p> <p>11 A Anything else that -- I'm sorry. Go ahead.</p> <p>12 Q That's okay.</p> <p>13 A It shows degradation.</p> <p>14 Q It shows degradation besides the SEM images?</p> <p>15 A No, degradation was assessed by SEM.</p> <p>16 Q Oxidation was assessed by FTIR?</p> <p>17 A That's correct. And there was XPS testing</p> <p>18 for some of those samples as well.</p> <p>19 Q You said there was XPS testing for some of</p> <p>20 the samples. What do you mean?</p> <p>21 A Well, I didn't say that very accurately. I</p> <p>22 can't remember all of the time points at</p> <p>23 which we ask did XPS. I know we did FTIR at</p> <p>24 zero, one, two, three, four and five. We did</p> <p>25 SEM at zero and five, but I can't remember</p>	<p>1 existence of carbon-oxygen bonds.</p> <p>2 Q Should there be no carbon-oxygen bonds?</p> <p>3 A There should be no carbon-oxygen bonds in</p> <p>4 nonoxidized polypropylene, polypropylene that</p> <p>5 has not been oxidized. I don't want to use</p> <p>6 pure, because there is other additives. But</p> <p>7 polypropylene that has not been oxidized</p> <p>8 should not reveal evidence of carbon-oxygen</p> <p>9 bonds.</p> <p>10 It's similar to FTIR, except FTIR is</p> <p>11 telling us the functional groups, and XPS is</p> <p>12 telling us the types of bonds.</p> <p>13 Q Were there any inconsistent findings in this</p> <p>14 test done by Dr. Dunn?</p> <p>15 A Not that I'm aware of.</p> <p>16 Q Did you put this -- the unstabilized</p> <p>17 polypropylene control, what was that control?</p> <p>18 A It was a polypropylene pellet that was</p> <p>19 purchased from a third-party vendor. I don't</p> <p>20 remember the name of the vendor, but I</p> <p>21 believe it is in Dr. Dunn's testing documents</p> <p>22 where the polypropylene has no antioxidant</p> <p>23 added to it.</p> <p>24 Q Are the documents in there that reflect what</p> <p>25 type of polypropylene pellet and where that</p>

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<p>1 pellet was from? Is that in the files?</p> <p>2 A I believe that it is. If it's not, we can</p> <p>3 get that. That's a known. Dr. Dunn has that</p> <p>4 information. And I should note that Dr. Dunn</p> <p>5 has all of the samples from this testing as</p> <p>6 well. We still have the material. We saved</p> <p>7 everything.</p> <p>8 Q Is it kept at his lab or his house?</p> <p>9 A I'm not sure where he is storing that, but he</p> <p>10 has stored that in dark containers protected</p> <p>11 from the light. He can speak to that. He's</p> <p>12 storing the material. I'm not sure where.</p> <p>13 Q So this polypropylene pellet that was used as</p> <p>14 an unstabilized control, am I correct that it</p> <p>15 had not been extruded or gone through any</p> <p>16 manufacturing process whatsoever?</p> <p>17 A I believe that it had probably at least been</p> <p>18 extruded because we bought it as pellets. So</p> <p>19 my understanding is they melt the</p> <p>20 polypropylene -- I don't know the answer to</p> <p>21 that. Dr. Dunn would be able to talk about</p> <p>22 the history of the sample.</p> <p>23 Q Do you know if this polypropylene pellet that</p> <p>24 you tested was a pellet used in any stress</p> <p>25 incontinence sling devices?</p>	<p>1 each time point because we have three or four</p> <p>2 replicates.</p> <p>3 I can't remember the exact number, but we</p> <p>4 have enough replicates that we can speak to</p> <p>5 the significant differences between groups</p> <p>6 as a function of time.</p> <p>7 Q But that analysis has not been done yet,</p> <p>8 correct?</p> <p>9 A It has not been done because we are still</p> <p>10 quantifying the results.</p> <p>11 Q Who will do the testing for clinical</p> <p>12 significance?</p> <p>13 A I don't know yet. We're still discussing</p> <p>14 this.</p> <p>15 Q Who are you considering to do statistical</p> <p>16 significance testing in this test --</p> <p>17 A Dr. Dunn or I. One of us will do it.</p> <p>18 Q Are you a statistician?</p> <p>19 A I'm not a statistician, but I've done similar</p> <p>20 statistical testing in any papers that I've</p> <p>21 published where we compared differences</p> <p>22 between material groups and time using a one-</p> <p>23 or two-way ANOVA. That's a common method.</p> <p>24 Q But you're going to be testing over different</p> <p>25 time points, correct?</p>
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<p>1 A I have no way of knowing that without knowing</p> <p>2 the supplier of the pellet.</p> <p>3 Q How was it that Dr. Dunn came to decide on</p> <p>4 which particular polypropylene pellet from a</p> <p>5 certain manufacturer he was going to obtain?</p> <p>6 A So in his previous testimony, Dr. Dunn has</p> <p>7 investigated a number of polypropylene cases,</p> <p>8 and he's done similar testing before in which</p> <p>9 he used unstabilized polypropylene controls,</p> <p>10 so that decision would have been based on his</p> <p>11 experience with prior testing.</p> <p>12 Q The unstabilized polypropylene control, what</p> <p>13 tests were done that on that?</p> <p>14 A The same tests as were done on TVT. So it</p> <p>15 would have been XPS, FTIR and SEM.</p> <p>16 Q Did you attempt to calculate any clinical</p> <p>17 significance of any findings in this test</p> <p>18 that Dr. Dunn did?</p> <p>19 A We are still doing the quantitative analysis,</p> <p>20 but we will calculate -- how shall I say this</p> <p>21 -- statistical significance between groups as</p> <p>22 a function of time. So we would compare the</p> <p>23 TVT group to the unstabilized polypropylene</p> <p>24 group. We would compare at each time point.</p> <p>25 And we would compare within each group at</p>	<p>1 A You mean statistically?</p> <p>2 Q Yeah.</p> <p>3 So you will be testing over multiple time</p> <p>4 points, correct?</p> <p>5 A Yes.</p> <p>6 Q So, therefore, you will need to apply a</p> <p>7 Bonferroni or some type of multiple testing</p> <p>8 equation, correct?</p> <p>9 A Yes. We typically do this. I believe it</p> <p>10 will be a two-way ANOVA with a Bonferroni</p> <p>11 correction. But, again, we haven't decided</p> <p>12 that yet.</p> <p>13 Q So as you sit here today, you cannot state</p> <p>14 that the test results were statistically</p> <p>15 significant upon applying the proper</p> <p>16 statistical testing?</p> <p>17 A We haven't done it yet. The differences</p> <p>18 appear to be large, but we have to do the</p> <p>19 statistics for the FTIR testing. I don't</p> <p>20 know what we will be able to do yet on the</p> <p>21 SEM. We are discussing that.</p> <p>22 Q So the FTIR testing is the testing that you</p> <p>23 intend to do statistical significance testing</p> <p>24 upon?</p> <p>25 A Yes.</p>

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<p>1 Q And the SEM images, because you only took</p> <p>2 them at limited time points, zero and five</p> <p>3 weeks, you do not know whether there is</p> <p>4 enough data to generate statistical</p> <p>5 significant findings?</p> <p>6 MR. KUNTZ: Objection.</p> <p>7 A I wouldn't say it that way. I would say in</p> <p>8 SEM, we are looking at specific locations.</p> <p>9 We can't sample the entire mesh area. So</p> <p>10 it's -- we're evaluating. We haven't decided</p> <p>11 yet what to do with it.</p> <p>12 BY MR. SNELL:</p> <p>13 Q Is it fair to say as you sit here today, you</p> <p>14 have not decided whether or not to do</p> <p>15 statistically significant calculations upon</p> <p>16 the SEM testing part of the test?</p> <p>17 A That's right.</p> <p>18 Q For the XPS portion of this test, have you</p> <p>19 attempted to do any statistical significance</p> <p>20 calculations?</p> <p>21 A Not yet. XPS is similar to SEM, in that</p> <p>22 we're limited to a relatively small area on</p> <p>23 the surface of the mesh, so we have a similar</p> <p>24 sampling concern. So we haven't yet decided</p> <p>25 -- with XPS we were more interested in</p>	<p>1 Q Well, you had a whole sling, correct?</p> <p>2 A Yes.</p> <p>3 Q That's enough to do molecular weight testing</p> <p>4 on, correct?</p> <p>5 A It's difficult for us because we have to send</p> <p>6 these samples off to an external laboratory</p> <p>7 that requires a rather large sample size.</p> <p>8 And we would also want to analyze the</p> <p>9 molecular weight of that outside degrade and</p> <p>10 surface layer would be the most informative.</p> <p>11 So then the material requirements for doing</p> <p>12 that testing are pretty limiting, so we</p> <p>13 didn't do it.</p> <p>14 We believed that the FTIR and the SEM</p> <p>15 would provide similar information about the</p> <p>16 breakdown in the structure at the surface.</p> <p>17 And FTIR and SEM are commonly used by many</p> <p>18 investigators in these types of studies. So</p> <p>19 that's why we did the study the way that we</p> <p>20 did.</p> <p>21 Q Is it correct or not that you had enough</p> <p>22 material, considering you had a whole sling,</p> <p>23 to look at the molecular weight?</p> <p>24 MR. KUNTZ: Objection.</p> <p>25 A I don't know that we did, because we would</p>
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<p>1 confirming the existence of those</p> <p>2 carbon-oxygen bonds.</p> <p>3 XPS is a useful technique for showing</p> <p>4 that the carbon is, in fact, chemically bound</p> <p>5 to the oxygen. And so we use XPS as a method</p> <p>6 to support the FTIR findings.</p> <p>7 Q But to date, no statistical significance</p> <p>8 testing has been done on the XPS portion; is</p> <p>9 that right?</p> <p>10 A It has not been done.</p> <p>11 Q Did you attempt to analyze molecular weight</p> <p>12 in this test?</p> <p>13 A We did not.</p> <p>14 Q Why not?</p> <p>15 A Molecular weight measurements require a</p> <p>16 considerable amount of material. Molecular</p> <p>17 weight measurements also aren't as -- with</p> <p>18 molecular weight, we are sampling the entire</p> <p>19 fiber. Whereas with these other methods,</p> <p>20 it's more the surface of the fiber. So it</p> <p>21 takes a lot of material, and it's difficult</p> <p>22 to isolate the effects of what's happening on</p> <p>23 the surface. In other words, it would take a</p> <p>24 lot of material to do that, and we didn't</p> <p>25 have that much.</p>	<p>1 have required separate replicates for that.</p> <p>2 And Dr. Dunn can speak to this better than I</p> <p>3 can, but there is not a lot of polymer in</p> <p>4 that -- I mean, it's a mesh. And so we</p> <p>5 needed to have separate replicates for the</p> <p>6 GPC. And we would have to have rather large</p> <p>7 samples in order to send them off for</p> <p>8 molecular weight analysis because we can't do</p> <p>9 it at Vanderbilt. We don't have the</p> <p>10 equipment.</p> <p>11 So it would have taken considerably more</p> <p>12 material, and I don't know that we had it.</p> <p>13 But, again, Dr. Dunn can speak to that.</p> <p>14 BY MR. SNELL:</p> <p>15 Q Do you know if Dr. Dunn has done molecular</p> <p>16 weight GPC testing on other mesh</p> <p>17 manufacturers' slings?</p> <p>18 A He has done some testing on exemplars in the</p> <p>19 past. But, again, my recollection of this is</p> <p>20 we had to send away a fairly significant</p> <p>21 amount of material. This is what I remember.</p> <p>22 Again, Dr. Dunn would be able to address that</p> <p>23 better.</p> <p>24 Q Did you discuss doing GPC molecular weight</p> <p>25 testing and decided not to do it or is this a</p>

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<p>1 test that just did not really enter into your</p> <p>2 mind?</p> <p>3 A Oh, we discussed it. We certainly discussed</p> <p>4 it. Our conclusion was with the amount of</p> <p>5 material that we had and the amount of time</p> <p>6 that we had, it made the most sense to focus</p> <p>7 on FTIR and SEM for this round of testing</p> <p>8 and XPS. We could do those tests with a</p> <p>9 single set of replicates and save those</p> <p>10 samples.</p> <p>11 Keep in mind too, I don't think I was</p> <p>12 very clear on this point. But when I say</p> <p>13 zero, one, two, three, four, five, that's</p> <p>14 separate materials for each time point</p> <p>15 multiplied by three or four replicates for</p> <p>16 each time point, so you can see this is</p> <p>17 getting to be a rather large number of mesh</p> <p>18 particles.</p> <p>19 Considering the time constraints we had,</p> <p>20 and the amount of material we had, we</p> <p>21 considered many different types of testing,</p> <p>22 XPS, DSC, all of this different testing that</p> <p>23 has been reported in the literature. We</p> <p>24 decided to focus on those three to answer the</p> <p>25 specific question of can it oxidize. FTIR</p>	<p>1 different reaction mechanism. But the end</p> <p>2 product is the same, these hydroxyl radicals.</p> <p>3 Q I think you said that you are doing this in</p> <p>4 vitro. That's not correct, is it?</p> <p>5 A Doing what in vitro?</p> <p>6 Q Let me back up. I heard you say something</p> <p>7 that just threw me off there.</p> <p>8 A Okay.</p> <p>9 Q When you put the TVT in this other control --</p> <p>10 can I call it a solution?</p> <p>11 A Yes.</p> <p>12 Q Is there a specific common name that I can</p> <p>13 use?</p> <p>14 A We can call it oxidative solution if you</p> <p>15 like.</p> <p>16 Q I don't like that.</p> <p>17 A You don't like that. Of course, you don't</p> <p>18 like that, do you?</p> <p>19 Q Try again.</p> <p>20 MR. BOWMAN: I've got a</p> <p>21 suggestion.</p> <p>22 MR. SNELL: What?</p> <p>23 MR. BOWMAN: The Anderson</p> <p>24 solution.</p> <p>25 THE WITNESS: We can call it the</p>
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<p>1 and XPS, we believe were probably the best</p> <p>2 choices for answering that question of can it</p> <p>3 oxidize because they're chemical analyses.</p> <p>4 That was the rationale for why we did it.</p> <p>5 Q This medium that you put the samples into</p> <p>6 which you believe mimics what a macrophage</p> <p>7 can produce in the body, what specific</p> <p>8 compounds or chemicals of the macrophage does</p> <p>9 this compound consist of?</p> <p>10 A I think I know what you mean. So the</p> <p>11 chemical reaction, cobalt chloride reacts</p> <p>12 with hydrogen peroxide. Again, hydrogen</p> <p>13 peroxide is a substrate for this enzyme,</p> <p>14 myeloperoxidase or MPO in the inflammatory</p> <p>15 cells. That chemical reaction produces</p> <p>16 hydroxyl radicals, OH radical. And those</p> <p>17 hydroxyl radicals are the species that attack</p> <p>18 the polypropylene as we've discussed</p> <p>19 previously.</p> <p>20 So it generates those hydroxyl radicals,</p> <p>21 which are a form of reactive oxygen species</p> <p>22 in the body. Instead of generating this</p> <p>23 reactive oxygen species through a</p> <p>24 myeloperoxidase catalyzed reaction in a cell,</p> <p>25 we are doing this reaction in vitro by</p>	<p>1 solution, that's fine.</p> <p>2 BY MR. SNELL:</p> <p>3 Q Let's get really simple, though. Just so I</p> <p>4 understand, that solution, what is it made</p> <p>5 of?</p> <p>6 A Okay. I can explain -- and, again, this is</p> <p>7 in the documents, but we mix a solution of</p> <p>8 cobalt chloride.</p> <p>9 Q Okay. So that's a molecule of cobalt bound</p> <p>10 with chloride?</p> <p>11 A I believe it's COCL₂. Is it CL₂ or CL₃? I</p> <p>12 can't -- it's cobalt chloride. It's either</p> <p>13 COCL₂ or CL₃. I just don't have it</p> <p>14 memorized. But cobalt chloride reacts with</p> <p>15 hydrogen peroxide, H₂O₂. So the solution is</p> <p>16 20 percent H₂O₂, hydrogen peroxide. I don't</p> <p>17 remember the concentration of cobalt</p> <p>18 chloride, but it's again in the SOP.</p> <p>19 We mix those together, and they react to</p> <p>20 give reaction products, including hydroxyl</p> <p>21 anion, that's OH minus. That's a basic</p> <p>22 solution. Plus OH radical, that's OH dot, so</p> <p>23 hydroxyl radical. And then there is a valence</p> <p>24 change on the cobalt. I can't remember the</p> <p>25 changes it's valenced.</p>

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<p>1 But the main reaction product is that</p> <p>2 hydroxyl radical that's simulating the</p> <p>3 reactive oxygen species formed by these</p> <p>4 inflammatory cells in vivo.</p> <p>5 Q Okay. So the hydroxyl radical simulates the</p> <p>6 reactive oxygen species from the macrophages</p> <p>7 in foreign body giant cells?</p> <p>8 A It is. So the foreign body giant cells and</p> <p>9 macrophages produce a number of reactive</p> <p>10 oxygen species, and hydroxyl radicals are one</p> <p>11 of them. So in the in vitro test, we are</p> <p>12 producing those hydroxyl radicals and the</p> <p>13 Bonferroni ROS species produced by the</p> <p>14 inflammatory cells in vivo or in vitro. They</p> <p>15 do this in vitro as well.</p> <p>16 Q How do you know that macrophages in foreign</p> <p>17 giant body cells produce hydroxyl radicals in</p> <p>18 any particular case?</p> <p>19 A It's been published in the Dr. Anderson</p> <p>20 papers that I mentioned that when these</p> <p>21 inflammatory cells adhere to the biomaterial</p> <p>22 surface, they secrete a number of these</p> <p>23 reactive oxygen species, including the</p> <p>24 hydroxyl radicals.</p> <p>25 Q How much hydroxyl radical do they produce?</p>	<p>1 implanted subcutaneously. That was -- the</p> <p>2 purpose of that control was to give us some</p> <p>3 idea of the relative time scale to relate our</p> <p>4 tests to in vivo conditions as an</p> <p>5 approximation.</p> <p>6 Q In vivo in a hamster, though, not a person?</p> <p>7 A Yes, in vivo in a hamster in a subcutaneous</p> <p>8 space, not the pelvic -- it could be much</p> <p>9 faster in a pelvic floor. But it was a</p> <p>10 suture implanted subcutaneously is what</p> <p>11 Liebert did.</p> <p>12 Q What is the rate of induction of Prolene</p> <p>13 polypropylene in the pelvic floor?</p> <p>14 A We cannot determine that from this test.</p> <p>15 There are many factors that affect that.</p> <p>16 Q Is it correct that you do not know how much</p> <p>17 of the hydroxyl radical is produced in the</p> <p>18 solution used by Dr. Dunn?</p> <p>19 A I'm not sure if that's known how -- no, I</p> <p>20 don't know that we know that, but --</p> <p>21 Q Well, let's see if we can do this. It would</p> <p>22 seem to me to be common sense that the amount</p> <p>23 of hydroxyl radicals that would be produced in</p> <p>24 vivo would be somewhat dependent upon the</p> <p>25 number of macrophages; is that correct?</p>
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<p>1 A I don't know that anybody has measured that.</p> <p>2 Q How much hydroxyl radical is produced in this</p> <p>3 test that mesh was put into?</p> <p>4 A We don't know. But the reason we ran the</p> <p>5 polypropylene control, I can try to answer</p> <p>6 that. So we know from Liebert, Liebert took</p> <p>7 the monofilament, the unstabilized</p> <p>8 polypropylene, and planted it subcutaneously</p> <p>9 in a hamster, and he saw a chemical</p> <p>10 induction. He saw oxidation induction of</p> <p>11 this oxidation reaction at 108 days. Okay.</p> <p>12 So in our study -- that is 108 days to</p> <p>13 induction. That is in vivo in that hamster</p> <p>14 model, in vivo in the hamster model. In our</p> <p>15 study, we saw induction between days 21 and</p> <p>16 28 for unstabilized polypropylene control.</p> <p>17 So if you average that, just to give you an</p> <p>18 approximation to try to answer your question,</p> <p>19 somewhere between 21 and 28 -- let's call</p> <p>20 that 25 days, and Liebert saw induction in</p> <p>21 vivo at around 100 days.</p> <p>22 That tells us that events are happening</p> <p>23 in our in vitro test about four times faster</p> <p>24 than they happen in that in vivo hamster</p> <p>25 model, which is a subcutaneous suture</p>	<p>1 A That would be one factor. The extent of the</p> <p>2 inflammatory reaction would be one factor</p> <p>3 that would affect induction time.</p> <p>4 Q So if there were 1,000 macrophages present,</p> <p>5 the ability of hydroxyl radicals to be</p> <p>6 produced quantity-wise would be much greater</p> <p>7 than if only ten macrophages were present.</p> <p>8 Is that a fair scientific statement?</p> <p>9 A You're saying that you would expect more ROS</p> <p>10 with more macrophages? Is that what you're</p> <p>11 saying?</p> <p>12 Q No.</p> <p>13 A Okay. Say it again. I didn't get it.</p> <p>14 Q The potential amount of hydroxyl radicals that</p> <p>15 could be produced would be higher if there</p> <p>16 were 1,000 macrophages present as opposed to</p> <p>17 only ten. Is that a fair scientific</p> <p>18 statement?</p> <p>19 A Present on like the --</p> <p>20 Q Present at the mesh, present at the tissues.</p> <p>21 A Per area of something like this, right?</p> <p>22 Q Per the same area?</p> <p>23 A Yeah. I mean, I think this is equivalent to</p> <p>24 what I said. If you have more macrophages</p> <p>25 per area, more foreign body giant cells, that</p>

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<p>1 is a factor. I mean, certainly that's a</p> <p>2 factor.</p> <p>3 But, again, I want to emphasize that the</p> <p>4 point of the tests was not to calculate the</p> <p>5 rate of -- at which through the time at which</p> <p>6 induction happens. It was just to answer</p> <p>7 this question, can it oxidize, can it become</p> <p>8 induced, can it degrade. That was the</p> <p>9 purpose of the tests.</p> <p>10 So we were not trying to say use these</p> <p>11 data to calculate the induction time of</p> <p>12 Prolene mesh in the vaginal space. There</p> <p>13 were a number of factors affecting this. All</p> <p>14 this test shows is that it happens. It can</p> <p>15 oxidize and degrade. That was the purpose.</p> <p>16 Q What is the size of the solution that you put</p> <p>17 the single TVT device in?</p> <p>18 A These were vials. I don't know. Maybe 20</p> <p>19 milliliter vials. I can't remember the size</p> <p>20 of them. They were maybe that tall and maybe</p> <p>21 that big around (indicating). They were</p> <p>22 vials.</p> <p>23 Q So you put a piece of the mesh in the vial,</p> <p>24 and the vial had the solution?</p> <p>25 A Yes.</p>	<p>1 things as well.</p> <p>2 I would rather say that there is lots of</p> <p>3 factors that can affect this. And it's</p> <p>4 basically accelerated by -- it happens about</p> <p>5 four times faster than what Liebert observed</p> <p>6 in that hamster model. I can say that. But</p> <p>7 how many macrophages, I -- we don't know how</p> <p>8 many macrophages Liebert observed. So it's</p> <p>9 very difficult to calibrate it to that level</p> <p>10 of detail.</p> <p>11 Does that make --</p> <p>12 Q I guess maybe if I can back up and just make</p> <p>13 this question as simple as possible.</p> <p>14 A Okay. Yeah.</p> <p>15 Q Are there any documents that are in those</p> <p>16 test files that say for this solution, for a</p> <p>17 given amount of the solution, that is the</p> <p>18 equivalent to the hydroxyl radicals that can</p> <p>19 be produced by Y number of macrophages?</p> <p>20 A I don't know that that correlation exists. I</p> <p>21 don't know.</p> <p>22 MR. SNELL: Okay. Let's take a</p> <p>23 break.</p> <p>24 (A brief recess is taken from</p> <p>25 3:25 to 3:45 p.m.)</p>
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<p>1 Q Were all of the vials filled with the same</p> <p>2 amount of solution?</p> <p>3 A Yes. I believe those -- I can't remember the</p> <p>4 number, but Dr. Dunn controlled for that.</p> <p>5 Q As you sit here, do you know how much</p> <p>6 solution was put in each bottle?</p> <p>7 A I don't remember the number. It was in the</p> <p>8 range of tens of milliliters. It wasn't more</p> <p>9 than 100. I don't remember the number.</p> <p>10 Dr. Dunn would know.</p> <p>11 MR. KUNTZ: Can we take a break?</p> <p>12 We've been going for one hour and 45 minutes,</p> <p>13 almost two hours.</p> <p>14 MR. SNELL: Yeah.</p> <p>15 BY MR. SNELL:</p> <p>16 Q One other question while we are taking about</p> <p>17 these vials and solutions. How many</p> <p>18 macrophages does one vial equate to?</p> <p>19 A I don't know the answer to that. The best</p> <p>20 way I can answer this -- and I want to be</p> <p>21 responsive. But the best way I can answer</p> <p>22 this is compared to Liebert, we are seeing an</p> <p>23 acceleration of about a factor of four.</p> <p>24 Could that mean that there is four times as</p> <p>25 many -- it could, but it could mean other</p>	<p>1 (Deposition Exhibit No. 3 is</p> <p>2 marked for identification.)</p> <p>3 BY MR. SNELL:</p> <p>4 Q Dr. Guelcher, we are back on the record. We</p> <p>5 have marked as Exhibit 3, the thumb drive,</p> <p>6 that has the different documents, reliance</p> <p>7 materials, etc., that you brought to the</p> <p>8 deposition, correct?</p> <p>9 A That's correct.</p> <p>10 Q And what we're doing now, we are looking</p> <p>11 under -- there is a folder called Guelcher</p> <p>12 Reliance Docs that we're going to look under.</p> <p>13 And we are going to look for test materials,</p> <p>14 correct?</p> <p>15 A That's correct.</p> <p>16 Q And then under that there is a subfolder</p> <p>17 called In Vitro Testing. Is that a folder</p> <p>18 that you're looking at?</p> <p>19 A Yes, I believe there is a folder called in</p> <p>20 vitro testing.</p> <p>21 Q And the in vitro testing folder has test</p> <p>22 information pertaining to this test that you</p> <p>23 testified about earlier where Dr. Dunn</p> <p>24 conducted the test on the single TVT</p> <p>25 retropubic device compared to the</p>

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<p>1 polypropylene pellet?</p> <p>2 A That's correct.</p> <p>3 Q Now, within that in vitro testing folder,</p> <p>4 there are additional subfolders, correct?</p> <p>5 A That's correct.</p> <p>6 Q All right. So where is the study protocol?</p> <p>7 A Okay. I'm going to have to look for that.</p> <p>8 MR. KUNTZ: Again, there is a</p> <p>9 folder called protocols.</p> <p>10 MR. SNELL: I hear you. I just</p> <p>11 want the witness to tell me that it's</p> <p>12 actually in there and show me where it is.</p> <p>13 A I'm looking. Okay. Study design and</p> <p>14 protocols. There is a folder called study</p> <p>15 design and protocols.</p> <p>16 BY MR. SNELL:</p> <p>17 Q Okay. Give me a second. I'm in the study</p> <p>18 design and protocols folder. And where is</p> <p>19 the study protocol?</p> <p>20 A Okay. There is -- I believe it's the</p> <p>21 oxidative media Preparation file. Let me</p> <p>22 look at that and I believe that is it. So</p> <p>23 that is what I was calling the SOP. It says,</p> <p>24 Guelcher labs standard operating procedure</p> <p>25 oxidative media preparation. This is how we</p>	<p>1 for that.</p> <p>2 Okay. So I found it. I believe the file</p> <p>3 is called in vitro mesh testing sample ID's.</p> <p>4 There is an Excel file in that same folder</p> <p>5 that we were talking about.</p> <p>6 Q Okay.</p> <p>7 A And you can see that all of the sample</p> <p>8 numbers are listed here. And if you scroll</p> <p>9 to the bottom of that spreadsheet, you will</p> <p>10 see procedure. And so if you look on the</p> <p>11 procedure, line number five, place 5</p> <p>12 milliliters of oxidative media in each file.</p> <p>13 So that would be -- and then he has notes on</p> <p>14 what he did. So it's 5 mils, approximately 5</p> <p>15 milliliters of the media, of solution, in</p> <p>16 each file.</p> <p>17 Q In Anderson's paper, did he use 5 milliliters</p> <p>18 of solution?</p> <p>19 A I don't remember the number that he used or</p> <p>20 that I used in my papers. I don't remember</p> <p>21 that number.</p> <p>22 Q Do you know if you deviated from the amount</p> <p>23 that Anderson used in this test?</p> <p>24 A I don't know. I'd have to check it.</p> <p>25 Q Did Dr. Dunn decide the procedure to use</p>
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<p>1 prepared the medium that you were asking me</p> <p>2 about.</p> <p>3 So it has the recipe for -- it's CoCL2,</p> <p>4 cobalt chloride hexahydrate, 30-percent</p> <p>5 hydrogen peroxide solution and water. And</p> <p>6 these materials are mixed to make the 1 liter</p> <p>7 master batch, and the procedures are all</p> <p>8 listed here for that. That is how we get the</p> <p>9 solution.</p> <p>10 Q And how much is put into each of the vials?</p> <p>11 A I will have to look at a different procedure,</p> <p>12 because I think this is just the master</p> <p>13 batch. Let me find it.</p> <p>14 Q Before you leave that document, at the bottom</p> <p>15 left it says, ADT dash last edit 9/15/14?</p> <p>16 A Yes.</p> <p>17 Q Who is ADT?</p> <p>18 A That's my graduate student, Anne Talley. She</p> <p>19 is the one who has been maintaining this</p> <p>20 draft that I have approved.</p> <p>21 You asked about what, how much is added,</p> <p>22 the volume?</p> <p>23 Q Yes, the volume added to the vial of the</p> <p>24 solution.</p> <p>25 A Okay. I am going to have to go back and look</p>	<p>1 approximately 5 milliliters of oxidated</p> <p>2 media in each file?</p> <p>3 A I don't know that the Anderson paper</p> <p>4 specified this level of detail. We did</p> <p>5 discuss this. The Anderson paper did not</p> <p>6 present a procedure in this level of detail</p> <p>7 that I remember, but I would have to confirm</p> <p>8 that by looking at the paper. Do you want me</p> <p>9 to do that?</p> <p>10 Q Who was it who decided to use 5 milliliters</p> <p>11 of oxidated media in each file?</p> <p>12 A I don't remember. We discussed this test. I</p> <p>13 don't remember discussing where exactly that</p> <p>14 came from. I know -- I'm trying to find</p> <p>15 this.</p> <p>16 Okay. Is there a question? What was the</p> <p>17 question? I don't remember. I thought I</p> <p>18 answered it, but I will answer it again.</p> <p>19 Q Let me just ask the question again. Who</p> <p>20 decided to use approximately 5 milliliters s</p> <p>21 of oxidated media to be put in into each</p> <p>22 vial?</p> <p>23 A I know we discussed this, but I don't</p> <p>24 remember the details. We discussed all of</p> <p>25 these points, and I just don't remember that,</p>

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<p>1 any more details than that.</p> <p>2 Q The same number of samples of unstabilized</p> <p>3 polypropylene control were not used as the</p> <p>4 TVT; is that correct?</p> <p>5 A I need to look at the spreadsheet again.</p> <p>6 Polypropylene standard -- you say the same --</p> <p>7 why -- I don't see that. Where are you</p> <p>8 looking?</p> <p>9 Q I'm looking at the Excel file you pointed out</p> <p>10 at above PP standard. Let's just make sure.</p> <p>11 Is the PP standard, is that the unstabilized</p> <p>12 polypropylene control?</p> <p>13 A Yes. And to get back to one of your previous</p> <p>14 questions, the MSDS and the supplier for that</p> <p>15 material is here.</p> <p>16 Q And so for the unstabilized polypropylene</p> <p>17 control, there were only 15 samples, correct?</p> <p>18 A Oh, I see the top of the column, 15 samples.</p> <p>19 That's probably because it became oxidized</p> <p>20 more quickly. I don't -- so we only went out</p> <p>21 to four weeks with the -- because it became</p> <p>22 induced faster, the 15 samples. I don't know</p> <p>23 the answer to that now, what the number of</p> <p>24 replicates for each time point was. I can't</p> <p>25 tell from this table.</p>	<p>1 something that Dr. Dunn did?</p> <p>2 A I can't remember the details of that decision</p> <p>3 right now.</p> <p>4 Q Who made the decision to only use 15 samples</p> <p>5 of the unstabilized polypropylene but 36</p> <p>6 samples of the TVT?</p> <p>7 A I don't remember those details either.</p> <p>8 Q When you do statistical analyses comparing</p> <p>9 the unstabilized polypropylene to the TVT,</p> <p>10 don't you have to take into account</p> <p>11 differences in sample sizes and differences</p> <p>12 in the quantity of time points analyzed?</p> <p>13 A Yeah, for comparing between -- for comparing</p> <p>14 between groups, those factors would have to</p> <p>15 be taken into account, but I just don't</p> <p>16 remember the details of that study design.</p> <p>17 Q Who did the FTIR testing?</p> <p>18 A Dr. Dunn.</p> <p>19 Q He personally did it or did he have somebody</p> <p>20 else do it?</p> <p>21 A I believe he did it. But, again, it was done</p> <p>22 through his company, so I don't know the</p> <p>23 details of who actually did what</p> <p>24 measurements, but I believe he did it.</p> <p>25 Q Do you know where this FTIR machine was that</p>
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<p>1 Q Why were there only 15 samples of the</p> <p>2 unstabilized polypropylene control, but 36</p> <p>3 samples of the TVT?</p> <p>4 A Well, one reason would be because we didn't</p> <p>5 do as many time points. We did four weeks,</p> <p>6 it looks like, instead of -- and I don't</p> <p>7 think that we did as much -- I spoke</p> <p>8 incorrectly. I think previously it appears</p> <p>9 that we actually had separate samples for XPS</p> <p>10 and FTIR, and it doesn't look like we had as</p> <p>11 many XPS samples. I would have to think</p> <p>12 about that.</p> <p>13 Q Do you know why you only analyzed the</p> <p>14 unstabilized polypropylene control out to</p> <p>15 four weeks, whereas you analyzed the TVT</p> <p>16 later?</p> <p>17 A It became induced faster, so the unstabilized</p> <p>18 control became induced between weeks three</p> <p>19 and four. So we didn't do as many time</p> <p>20 limits.</p> <p>21 Q You could have still tested it, though, at</p> <p>22 five and six weeks, right?</p> <p>23 A We could have.</p> <p>24 Q Did you make an affirmative decision not to</p> <p>25 test at four and five weeks or is that</p>	<p>1 was used in this test?</p> <p>2 A Yes. It's in his laboratory.</p> <p>3 Q So he used the Vanderbilt lab FTIR machine</p> <p>4 for the test?</p> <p>5 A Well, I would say he used the FTIR in his</p> <p>6 laboratory at Vanderbilt.</p> <p>7 Q Did he buy that FTIR machine?</p> <p>8 A He would have to speak to the details of</p> <p>9 that.</p> <p>10 Q I guess the question is -- you took issue</p> <p>11 with whether I asked you -- do you know who</p> <p>12 owns that FTIR machine? Is it Vanderbilt or</p> <p>13 Dr. Dunn or --</p> <p>14 A I don't know the details of that. When you</p> <p>15 said the Vanderbilt lab, that was, I thought,</p> <p>16 a little vague. I wanted to clarify that it</p> <p>17 was -- it's in his laboratory space that he</p> <p>18 has been assigned at Vanderbilt.</p> <p>19 Q Okay.</p> <p>20 A That's what I meant.</p> <p>21 Q All right. But it very well could be that</p> <p>22 that is a machine that is actually owned by</p> <p>23 Vanderbilt?</p> <p>24 A I don't know the details. As I said,</p> <p>25 Dr. Dunn has an agreement with the</p>

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<p>1 university. That's all I know. He would</p> <p>2 have to speak as to the rest of it.</p> <p>3 Q Now, the SEM analysis, whose SEM machine was</p> <p>4 used?</p> <p>5 A There is an SEM instrument and it's an</p> <p>6 institutional resource. It's a shared</p> <p>7 resource is perhaps a better way of saying</p> <p>8 it, and so we pay for machine time.</p> <p>9 Q Is it located at Vanderbilt?</p> <p>10 A It is.</p> <p>11 Q In what school?</p> <p>12 A Well, it's an institute, so it's between</p> <p>13 schools and the members of the school of</p> <p>14 engineering, college of arts and science,</p> <p>15 medicine. It's a shared resource.</p> <p>16 Q It's not in Dr. Dunn's lab?</p> <p>17 A No.</p> <p>18 Q Physically where is it? Is it within a</p> <p>19 building in the department of medicine?</p> <p>20 Department of engineering?</p> <p>21 A Again, it's a building that has shared space</p> <p>22 between the college of arts and science and</p> <p>23 the school of engineering.</p> <p>24 Q Who did the SEM images?</p> <p>25 A Again, it was Dr. Dunn's company. Whether he</p>	<p>1 expertise. She has a lot of experience with</p> <p>2 it.</p> <p>3 Q Is Dr. Rogers an expert for plaintiffs in</p> <p>4 transvaginal mesh litigation that you're</p> <p>5 aware of?</p> <p>6 A Not to my knowledge. She was contracted by</p> <p>7 Dr. Dunn to do the work.</p> <p>8 Q Do you know how much she was paid by</p> <p>9 Dr. Dunn?</p> <p>10 A I don't know the details of that. Probably</p> <p>11 the same as my arrangement, but I don't know.</p> <p>12 Q Was she aware of Dr. Dunn's role as an expert</p> <p>13 in transvaginal mesh litigation?</p> <p>14 A Yes, she was, to my knowledge.</p> <p>15 Q She is aware that Dr. Dunn is being paid by</p> <p>16 attorneys for plaintiffs in transvaginal mesh</p> <p>17 litigation?</p> <p>18 A I believe she would.</p> <p>19 Q So when she sat down to do this XPS analysis,</p> <p>20 she knew that the money was coming from</p> <p>21 plaintiffs' lawyers in transvaginal mesh</p> <p>22 litigation?</p> <p>23 A Yes, I believe she knew that. I haven't --</p> <p>24 I'm hesitating because I can't remember</p> <p>25 explicitly discussing that with her, but I</p>
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<p>1 had an employee doing that, I don't know. He</p> <p>2 was responsible for all of that.</p> <p>3 Q The XPS machine that was used to look at the</p> <p>4 sample, where is that machine?</p> <p>5 A So that machine is also administered by the</p> <p>6 institute I was referring to earlier. It's</p> <p>7 housed in the laboratory of Professor Bridget</p> <p>8 Rogers. So to clarify just for the record</p> <p>9 one of the earlier questions about who else</p> <p>10 at Vanderbilt was involved, Professor Bridget</p> <p>11 Rogers is a professor, an associate professor</p> <p>12 of chemical and biomolecular engineering, and</p> <p>13 she did the XPS testing.</p> <p>14 That slipped my mind earlier, I'm sorry,</p> <p>15 until we talked about it now.</p> <p>16 Q So Dr. Rogers was actually the one who did</p> <p>17 the XPS testing on this single TVT retropubic</p> <p>18 device and the unstabilized polypropylene</p> <p>19 control?</p> <p>20 A She did.</p> <p>21 Q Were you there when she did the testing?</p> <p>22 A No, but I don't need to be there when she --</p> <p>23 it's a -- she ran it and --</p> <p>24 Q Why didn't you do the XPS testing?</p> <p>25 A That's Dr. Rogers' particular area of</p>	<p>1 believe based on conversations with Russell</p> <p>2 that she knew she was being paid by</p> <p>3 litigation.</p> <p>4 Q Did Dr. Dunn have a conversation with</p> <p>5 Dr. Rogers about doing this XPS testing?</p> <p>6 A Yes.</p> <p>7 Q Were you present at the time of that</p> <p>8 conversation?</p> <p>9 A For some of the conversations, we did discuss</p> <p>10 it as a group with Professor Rogers. Was I</p> <p>11 there for every conversation, I can't say</p> <p>12 that I was. I did discuss this with</p> <p>13 Professors Dunn and Rogers.</p> <p>14 Q And what was said?</p> <p>15 A Well, we discussed how to do the analysis,</p> <p>16 what we were looking for, how we wanted to do</p> <p>17 the experiment, and what the goal was. We</p> <p>18 discussed the approach for the measurements.</p> <p>19 Q Who paid for the SEM time?</p> <p>20 A Again, I can't answer that -- oh, for the</p> <p>21 SEM. I'm sorry. I believe that Dr. Dunn has</p> <p>22 a sponsor research agreement through the</p> <p>23 university in which he set up a cost center.</p> <p>24 But, again, he has to speak to all of this.</p> <p>25 I believe it was paid for by the litigation</p>

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<p>1 through a center number from the university.</p> <p>2 Q What do you mean by center number?</p> <p>3 A Well, when we do internal billing within the</p> <p>4 university, we have cost centers associated</p> <p>5 with different funding sources. So he would</p> <p>6 have used the cost center associated with his</p> <p>7 sponsored research agreement. But, again, I</p> <p>8 am hesitant to go -- it's his project. I</p> <p>9 don't know the details of that.</p> <p>10 Q Who paid Dr. Rogers for her time?</p> <p>11 A Dr. Dunn. She invoiced Dr. Dunn, and then</p> <p>12 Dr. Dunn invoiced plaintiff's counsel.</p> <p>13 Q How much did Dr. Rogers' invoice in</p> <p>14 connection with this test that you're relying</p> <p>15 on?</p> <p>16 A I don't know the answer to that.</p> <p>17 Q Do you know how much Dr. Dunn has invoiced in</p> <p>18 connection with this test that you're relying</p> <p>19 on?</p> <p>20 A I haven't seen his invoices. I don't know.</p> <p>21 Q Would it be based on your understanding more</p> <p>22 than \$50,000 as an accurate prediction?</p> <p>23 A I don't know. I can't put a number on it</p> <p>24 because I didn't see the invoices.</p> <p>25 Q For the use of the XPS machine, am I correct</p>	<p>1 Q These aren't the same pellets that are used</p> <p>2 in the TVT device, correct?</p> <p>3 A Not to my knowledge.</p> <p>4 Q What is isotactic polypropylene?</p> <p>5 A That is just a reference to the structure of</p> <p>6 the polypropylene. Most polypropylene is</p> <p>7 sold commercially. And my understanding is</p> <p>8 isotactic is the most common isomer. I will</p> <p>9 say to my knowledge that polypropylene used</p> <p>10 to make Prolene is also isotactic, if that</p> <p>11 helps.</p> <p>12 Q Are you certain of that?</p> <p>13 A Pretty certain. I believe that's the case.</p> <p>14 Q Section 9 has different physical and chemical</p> <p>15 properties of this unstabilized polypropylene</p> <p>16 control?</p> <p>17 A Section 9, yes.</p> <p>18 Q Do you know if these properties are in any</p> <p>19 way different than the polypropylene pellets</p> <p>20 that are used in the TVT device?</p> <p>21 A Could you ask that again? I didn't catch it.</p> <p>22 Q Sure.</p> <p>23 For the chemical and physical properties</p> <p>24 of the unstabilized polypropylene control</p> <p>25 that you used, are you aware if the</p>
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<p>1 that someone would have to pay for that time</p> <p>2 or usage as well?</p> <p>3 A I don't know the details of that arrangement</p> <p>4 with the XPS with Dr. Rogers. I can't speak</p> <p>5 to that.</p> <p>6 Q The unstabilized polypropylene control, is</p> <p>7 that contained within the file that says</p> <p>8 polypropylene standard MSDS?</p> <p>9 A You were interested about the source?</p> <p>10 Q Yes.</p> <p>11 A Yes, I believe that it is, and I'm going to</p> <p>12 look at it right now. So this is the file,</p> <p>13 polypropylene standard MSDS, and I'm clicking</p> <p>14 on this link.</p> <p>15 Okay. This is an MSDS. I believe it is</p> <p>16 the polypropylene standard. If you see the</p> <p>17 ingredient, it says isotactic polypropylene</p> <p>18 at 100 percent. So this would be the</p> <p>19 unstabilized polypropylene control. It was</p> <p>20 purchased from Scientific Polymer Products,</p> <p>21 Incorporated, and that would be the MSDS for</p> <p>22 that material.</p> <p>23 Q And this is the pellets that you were talking</p> <p>24 about?</p> <p>25 A Yes.</p>	<p>1 properties are any different than the same</p> <p>2 properties for the pellets that are</p> <p>3 specifically used in the TVT device?</p> <p>4 A These properties appear to me to be very</p> <p>5 similar. If I'm looking at Sections 9 and</p> <p>6 10, the melting point of 160 degrees. This</p> <p>7 is the melting point I remember for Prolene</p> <p>8 from some of the internal documents, the</p> <p>9 saline water is negligible.</p> <p>10 If we look at stability and reactivity,</p> <p>11 it also says materials to avoid, oxidizing</p> <p>12 materials. It looks very much like something</p> <p>13 I would see for the MSDS for the</p> <p>14 polypropylene used to make Prolene that I</p> <p>15 saw. So to answer to your question, I would</p> <p>16 say it looks similar to me.</p> <p>17 Q And for the SEM test results that you --</p> <p>18 A Did you open the file? Is that where you</p> <p>19 are?</p> <p>20 Q Yeah, I was going to ask you. The SEM test</p> <p>21 results you believe showed pitting and you</p> <p>22 said peeling. Would those be found in that</p> <p>23 folder PCT-168SEM?</p> <p>24 A I'm looking. SEM, yes.</p> <p>25 Did you have a question or --</p>

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<p>1 Q I am just trying to see, are the SEM images</p> <p>2 that you referenced in that file PCT-168SEM?</p> <p>3 A I'm looking at a file TVT five week SEM PDF.</p> <p>4 I'm not sure what you're asking me. If you</p> <p>5 can just ask me again what you're looking</p> <p>6 for.</p> <p>7 Q The particular SEM images that you referenced</p> <p>8 that you be believed showed pitting or the</p> <p>9 peeling?</p> <p>10 A Yes.</p> <p>11 MR. KUNTZ: I will object. But</p> <p>12 go ahead.</p> <p>13 A Okay. So I'm looking at this. I'm in this</p> <p>14 SEM directory. I'm clicking On TVT five</p> <p>15 weeks. There is a folder called TVT five</p> <p>16 weeks, and I believe these are individual</p> <p>17 files. And then I believe this file TVT SEM,</p> <p>18 TVT five weeks SEM PDF, I believe that that</p> <p>19 is the file I was talking about earlier.</p> <p>20 So when I open this file, I see a number</p> <p>21 of SEM images of PET that show that there is</p> <p>22 a pitting and flaking on the surface of the</p> <p>23 TVT. That's what I was describing earlier.</p> <p>24 BY MR. SNELL:</p> <p>25 Q On the second photo -- can you look at my</p>	<p>1 Q This does not show anything like that,</p> <p>2 correct?</p> <p>3 A We don't see the cracking because we did not</p> <p>4 apply -- these materials are not under</p> <p>5 tension. There is no residual strain. So in</p> <p>6 the Anderson paper 1993, they prestressed the</p> <p>7 materials. And when they did this -- and</p> <p>8 they incubated them in an oxidative medium.</p> <p>9 When they did this, they were able to see</p> <p>10 environmental stress cracking.</p> <p>11 We did not prestress the materials.</p> <p>12 Again, the question was really to answer can</p> <p>13 it oxidize. So without that mechanical</p> <p>14 stress, we see more of these effects of</p> <p>15 peeling and blistering. And this is</p> <p>16 described in a number of papers to see</p> <p>17 environmental stress cracking you need a</p> <p>18 combination of three things. One is an</p> <p>19 oxidative medium, the second is a material</p> <p>20 that degrades in response to that medium, and</p> <p>21 the third is mechanical stress.</p> <p>22 So that -- there is no mechanical stress</p> <p>23 in this experiment, which would be why I</p> <p>24 don't believe we were seeing the transverse</p> <p>25 cracking as noticed in Clave and other</p>
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<p>1 computer?</p> <p>2 A The second photo is called PCT168SEM007.</p> <p>3 Q Yes, that's what I'm looking at.</p> <p>4 A Okay.</p> <p>5 Q And towards the middle, that's a fiber that</p> <p>6 we're looking at?</p> <p>7 A Yes, that's a specific fiber.</p> <p>8 Q Take a look towards the middle at the bottom,</p> <p>9 if you can look at what I'm looking at.</p> <p>10 Right here.</p> <p>11 A Yes.</p> <p>12 Q Right above the times 400.</p> <p>13 A Yes.</p> <p>14 Q And then moving directly north in the middle</p> <p>15 here. What is that?</p> <p>16 A That looks to me like an area that I would</p> <p>17 call degradation, where the surface is</p> <p>18 changing. It looks like there is some</p> <p>19 pitting and some residue, blistering perhaps.</p> <p>20 That looks like an area of surface</p> <p>21 degradation.</p> <p>22 Q In the SEM photos that I've seen in the</p> <p>23 literature, those typically show cracks</p> <p>24 running horizontal, correct?</p> <p>25 A That's right.</p>	<p>1 papers.</p> <p>2 Q Isn't another just as plausible answer that</p> <p>3 there is no proteins and biofilm on these</p> <p>4 images?</p> <p>5 A Not in my opinion.</p> <p>6 Q Let me ask you, were proteins and biofilm</p> <p>7 actually put on your samples of the TVT</p> <p>8 device?</p> <p>9 A So I want to be specific about this term</p> <p>10 biofilm. Biofilm is a polysaccharide matrix.</p> <p>11 It's deposited by bacteria. To me that's</p> <p>12 different than protein absorption. And I'm</p> <p>13 not aware of papers that are saying protein</p> <p>14 absorption is causing cracking. I mean, but</p> <p>15 the biofilm to me is the polysaccharide</p> <p>16 matrix deposited by bacteria.</p> <p>17 Protein absorption is something</p> <p>18 different, but it -- I mean, the surface is</p> <p>19 degrading here is what I see in response to</p> <p>20 the chemical induction is how I interpret</p> <p>21 these events.</p> <p>22 Q There is no cracking in your photos of the</p> <p>23 SEMs similar to those seen in the body as in</p> <p>24 Clave and Costello and de Tayrac, correct?</p> <p>25 A Again, there is no cracking here because</p>

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<p>1 these materials were not under any mechanical</p> <p>2 stress. There was no force. They weren't</p> <p>3 pre-strained like in the '93 Anderson paper.</p> <p>4 This is a protocol that was used in the '97</p> <p>5 Anderson paper to answer the question of</p> <p>6 oxidation. We didn't have mechanical</p> <p>7 strengths, and that's why we're not seeing</p> <p>8 cracking.</p> <p>9 Q You would agree that another plausible</p> <p>10 explanation for why you don't see cracking is</p> <p>11 there was no biofilm used in your testing?</p> <p>12 MR. KUNTZ: Objection.</p> <p>13 A I don't agree with that.</p> <p>14 BY MR. SNELL:</p> <p>15 Q Have you seen anywhere in the literature</p> <p>16 during your analyses where cracking was seen</p> <p>17 on an explant, and upon cleaning the explant,</p> <p>18 it was determined that biofilm was the source</p> <p>19 of the cracking? First of all, have you seen</p> <p>20 that in the literature?</p> <p>21 MR. KUNTZ: Objection. Go</p> <p>22 ahead.</p> <p>23 A I believe the paper you're talking about that</p> <p>24 I've seen was -- and correct me if I'm</p> <p>25 describing the wrong paper, but I have seen a</p>	<p>1 show the cracks. And then after they have</p> <p>2 cleaned off the biofilm, you know, it was</p> <p>3 clear that the filaments were fine?</p> <p>4 A Yes, but I think this is a different</p> <p>5 question. I agree with what that paper is</p> <p>6 saying in that -- we can pull it up and look</p> <p>7 at it again. I'm going on my memory, but I</p> <p>8 think it was only 30 days. And I have done</p> <p>9 these experiments myself. I've contaminated</p> <p>10 scaffolds and placed them in -- I just</p> <p>11 published a paper on this last year -- we</p> <p>12 placed it in a bone defect.</p> <p>13 We come back four weeks later, and we see</p> <p>14 a biofilm, and it looks a lot like that</p> <p>15 biofilm. And they clean it off, and, yeah,</p> <p>16 there is no damage to the polypropylene</p> <p>17 because it was only 30 days. It was a very</p> <p>18 short period of time. And as we've been</p> <p>19 discussing from Liebert and some of these</p> <p>20 other papers, we wouldn't -- scientifically,</p> <p>21 polypropylene would be induced at around 100</p> <p>22 days.</p> <p>23 So it's not too surprising to me that in</p> <p>24 30 days, the polypropylene hasn't started to</p> <p>25 crack yet. That's a very early time point.</p>
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<p>1 paper where the mesh was challenged with</p> <p>2 bacteria. We have a contaminated mesh. And</p> <p>3 then the SEM images I saw -- this is only 30</p> <p>4 days, and this SEM image showed what appeared</p> <p>5 to be a biofilm, which I would expect,</p> <p>6 because it was challenged with bacteria, and</p> <p>7 that biofilm showed cracks. But it looked</p> <p>8 like a biofilm. It didn't look like the SEM</p> <p>9 images in Clave. And some of the other</p> <p>10 explanted mesh papers don't look like</p> <p>11 biofilms to me.</p> <p>12 We can look at that paper. It's in my</p> <p>13 reliance materials. I can look for it, but I</p> <p>14 believe that's the paper you're referring to,</p> <p>15 and I have considered that. I believe that's</p> <p>16 a biofilm. And if you wash that biofilm off,</p> <p>17 it goes away, and there is no damage to</p> <p>18 underlying substrate, because it's only 30</p> <p>19 days. And so these events may not have</p> <p>20 started happening yet, because 30 days is a</p> <p>21 relative short period of time. That's my</p> <p>22 explanation of the paper that I believe</p> <p>23 you're referring to.</p> <p>24 Q It's the de Tayrac paper. You're aware of</p> <p>25 that? There is actually images where they</p>	<p>1 That's the way I understand that paper. But,</p> <p>2 again, I would be happy talk about it with</p> <p>3 you, but that's my memory of that paper.</p> <p>4 Q Do we know how much the Prolene polypropylene</p> <p>5 is induced at 120 days?</p> <p>6 A I think I know what you're getting at, but I</p> <p>7 would like you to ask it a different way.</p> <p>8 Induction time, it's an event, so we can't</p> <p>9 say how much it's induced. We can say either</p> <p>10 it's become induced or it has not. So are</p> <p>11 you asking -- I guess I'm not sure what</p> <p>12 you're asking.</p> <p>13 Q What is the significance of induction?</p> <p>14 A So it's described in many of my reliance</p> <p>15 materials. But an induction -- just to think</p> <p>16 of a plot, we see a small change in</p> <p>17 properties. So it's oxidizing, because there</p> <p>18 is adherent macrophages in giant cells, and</p> <p>19 it's oxidizing.</p> <p>20 And then we reach this point where the</p> <p>21 reaction becomes autocatalytic, and there is</p> <p>22 a very strong increase in the slope, kind of</p> <p>23 like hockey-stick applied. And that change</p> <p>24 in the slope, we refer to as the chemical</p> <p>25 induction time. So it's an event.</p>

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<p>1 So to say how much it is induced, I'm --</p> <p>2 I'm trying to explain why I can't answer that</p> <p>3 question.</p> <p>4 Q When does that chemical induction time take</p> <p>5 place with the Prolene polypropylene?</p> <p>6 A We talked about this earlier. It's difficult</p> <p>7 to -- when that happens in the body is going</p> <p>8 to be affected by a number of factors. But</p> <p>9 it's -- I think it's unlikely that that would</p> <p>10 happen in 30 days. That's very early. And</p> <p>11 that's why I explained the biofilm -- it</p> <p>12 could happen maybe in some conditions in 30</p> <p>13 days, but I don't believe in that experiment.</p> <p>14 Q Is there a certain point in which it becomes</p> <p>15 significant?</p> <p>16 A What becomes significant?</p> <p>17 Q This induction.</p> <p>18 A Well, it's an event. So at induction, there</p> <p>19 is dramatic changes in physical properties.</p> <p>20 But embrittlement in these events can happen</p> <p>21 even before induction. But, again, that</p> <p>22 experiment is just -- they have this one --</p> <p>23 it only went out to 30 days, and I just don't</p> <p>24 think they went far enough to see the stress</p> <p>25 cracking.</p>	<p>1 Q Under PCT 168 XPS --</p> <p>2 A Oh, you're on the XPS now.</p> <p>3 Q I'm in a Document 11062014 PCT 168 report.</p> <p>4 A Are you looking at the XPS report?</p> <p>5 Q Yes. This is actually from Bridget Rogers.</p> <p>6 A Okay. I am pulling up the report.</p> <p>7 Q On the second page, table one, it says</p> <p>8 fraction of carbon atoms bonded in the RCOOH</p> <p>9 and the CO configuration?</p> <p>10 A Right.</p> <p>11 Q What is that RCOOH?</p> <p>12 A So RCOOH is the hydroperoxide group that's</p> <p>13 formed when the polypropylene is oxidized.</p> <p>14 It's an intermediate in that complex reaction</p> <p>15 mechanism.</p> <p>16 Q And what does it mean when there is zeros in</p> <p>17 this table?</p> <p>18 A So if it's a zero, that means that in that</p> <p>19 particular spot she was looking at under the</p> <p>20 microscope, there was no oxidized</p> <p>21 polypropylene. In that particular spot, the</p> <p>22 polypropylene had not been oxidized. And</p> <p>23 then where we see the numbers is where we see</p> <p>24 evidence of oxidation of the polypropylene.</p> <p>25 Q What does the C equal sign --</p>
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<p>1 Q I'm looking here, and there is a folder</p> <p>2 called TVT six week SEM?</p> <p>3 A Yes.</p> <p>4 Q That would be the six-week images?</p> <p>5 A Let me open that. Let me pull it up. I</p> <p>6 think that is what it is, but -- yes, that</p> <p>7 would be the six-week images.</p> <p>8 Q Why were SEMs only done on some of the</p> <p>9 samples?</p> <p>10 A We were limited by the number of samples and</p> <p>11 just the amount of time to get this work</p> <p>12 done. And so we know that, as I was just</p> <p>13 explaining, once we reach the induction time,</p> <p>14 that we would expect to see these significant</p> <p>15 physical changes, physical degradation.</p> <p>16 And when the FTIR measurements told us</p> <p>17 that it was induced between weeks four and</p> <p>18 five, we did SEM images at week five, and</p> <p>19 then compared to the pristine sample, because</p> <p>20 we were comparing the period in which it's</p> <p>21 become induced. We still have the samples, I</p> <p>22 believe.</p> <p>23 And I think we did this really out of</p> <p>24 time constraints because there was so many</p> <p>25 samples.</p>	<p>1 A That's a carbonyl bond. That's also a</p> <p>2 reaction product.</p> <p>3 Q Why is there supposedly a carbonyl bond in</p> <p>4 sample two in one week?</p> <p>5 A I'm not sure.</p> <p>6 Q That makes no sense base on the literature</p> <p>7 and data as you understand it, correct?</p> <p>8 A I wouldn't say it makes no sense. I mean, it</p> <p>9 could be that small regions of the</p> <p>10 polypropylene are oxidized before they were</p> <p>11 implanted. We have seen that in other</p> <p>12 exemplars. It is possible that there is</p> <p>13 oxidation on the mesh before it's even</p> <p>14 implanted</p> <p>15 Q Where would that oxidation come from on the</p> <p>16 mesh?</p> <p>17 A Thermal processing. When it's extruded and</p> <p>18 processed at high temperatures, if those</p> <p>19 antioxidants get depleted, it's not</p> <p>20 surprising to me that you would see regions</p> <p>21 -- we have seen it on exemplars. And I can't</p> <p>22 say which meshes, but it's possible for the</p> <p>23 mesh to be oxidized during processing.</p> <p>24 Q Is it your opinion that this shows the TVT</p> <p>25 mesh is thermally oxidized?</p>

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<p>1 A That's not what I'm saying. I'm saying that</p> <p>2 that could be an explanation for why that</p> <p>3 number is not zero.</p> <p>4 Q Another explanation could be that her test is</p> <p>5 just wrong, correct?</p> <p>6 MR. KUNTZ: Objection.</p> <p>7 A I wouldn't say it's just wrong. I would say</p> <p>8 that when you look at the XPS as a whole,</p> <p>9 it's consistent with the FTIR data. We see</p> <p>10 regions of oxidation, and those numbers</p> <p>11 generally increase with time. And that point</p> <p>12 at one week -- yeah, there could be multiple</p> <p>13 explanations for that.</p> <p>14 BY MR. SNELL:</p> <p>15 Q You would not expect to see a reading at one</p> <p>16 week for the CO bond, correct?</p> <p>17 A No, not if -- I mean, if it had regions of</p> <p>18 oxidation, that could happen. It could have</p> <p>19 been that in that particular measurement, she</p> <p>20 was looking at a region that hadn't been</p> <p>21 oxidized during processing. That can't be</p> <p>22 ruled out.</p> <p>23 Q Well, what are all the possible reasons why</p> <p>24 you could find this CO finding in the second</p> <p>25 TVT sample at week one, besides there could</p>	<p>1 A She said that's what she saw. She trusts her</p> <p>2 methods. She stands by her methods. I'm not</p> <p>3 shocked, because as I said, we have</p> <p>4 sufficient oxidation in these meshes. The</p> <p>5 exemplars, you open them out of the box, and</p> <p>6 in some cases, we have seen oxidation. So</p> <p>7 I'm not shocked by this.</p> <p>8 Q Is it correct that one explanation could be</p> <p>9 that something was wrong with her equipment</p> <p>10 on that date, with the calibration or the</p> <p>11 test methods she did on that particular</p> <p>12 sample?</p> <p>13 A It's a possibility, but an unlikely one.</p> <p>14 Q Did you go back and look at any documents or</p> <p>15 any log books or anything like that with</p> <p>16 regard to what happened during that testing</p> <p>17 on week one?</p> <p>18 A We looked at -- Dr. Dunn and I and Dr. Rogers</p> <p>19 reviewed a fair amount of the original data,</p> <p>20 which she showed us the peaks in the XPS</p> <p>21 spectra.</p> <p>22 She has an algorithm for separating the</p> <p>23 peaks, as described in her report, and that's</p> <p>24 what she saw. And, again, this is looking</p> <p>25 through a microscope at one small spot on the</p>
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<p>1 be thermal oxidation that you're saying, I</p> <p>2 guess?</p> <p>3 Could her equipment not be calibrated or</p> <p>4 running properly on that certain day?</p> <p>5 A I think that is pretty unlikely. I think</p> <p>6 that it could be that there was a region in</p> <p>7 the mesh where the antioxidants had been</p> <p>8 depleted and oxidized very quickly. It could</p> <p>9 have happened during thermal oxidation. I</p> <p>10 mean, those are some examples of what could</p> <p>11 have happened.</p> <p>12 But I don't think one data point that is</p> <p>13 somewhat unexpected can be used to support</p> <p>14 the notion that the method is flawed. You</p> <p>15 can't rule out that the polypropylene wasn't</p> <p>16 oxidized. You simply can't really explain</p> <p>17 that data point. There is several possible</p> <p>18 reasons, and none of them is terribly</p> <p>19 conclusive.</p> <p>20 Q Did you ask her why in the world, Doctor, are</p> <p>21 you showing a positive finding in one week in</p> <p>22 the CO bond in the second sample?</p> <p>23 A We discussed it with her.</p> <p>24 Q But what did she say about why that finding</p> <p>25 was there at one week?</p>	<p>1 surface, and she saw this region where there</p> <p>2 was some evidence of oxidation.</p> <p>3 Q How small of a spot was that?</p> <p>4 A I don't know the size of the spot, but I know</p> <p>5 that she does this through a microscope.</p> <p>6 Q Do you have an idea or a range? I mean, are</p> <p>7 we talking about couple of microns or 1,000</p> <p>8 microns?</p> <p>9 A It's not -- you know, 1,000 microns would be</p> <p>10 a millimeter. It's not that big. I don't</p> <p>11 know the exact size of the spot.</p> <p>12 Q There were no positive findings at week two,</p> <p>13 correct?</p> <p>14 A When you say positive, there was no evidence</p> <p>15 -- none of the spots she looked at at week</p> <p>16 two showed evidence of oxidation. That's the</p> <p>17 way I would describe that.</p> <p>18 Q And how do you explain that?</p> <p>19 A Well, because she didn't see any evidence of</p> <p>20 carbon-oxygen bonds at week two on any of the</p> <p>21 spots she looked at.</p> <p>22 Q On week three, there were only two findings</p> <p>23 that were positive, correct?</p> <p>24 A On week three, there were two spots where she</p> <p>25 saw evidence of oxidation.</p>

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<p>1 Q On week three, second sample, it says 0.0088.</p> <p>2 What does that mean?</p> <p>3 A Let me look at her report in a little more</p> <p>4 detail and make sure I answer that correctly.</p> <p>5 So table one presents the fraction of</p> <p>6 carbon atoms bonded in the RCOOH and RCO</p> <p>7 configurations. So that would be -- the</p> <p>8 fraction of carbon atoms for that would be 88</p> <p>9 percent of the carbon atoms would bond to</p> <p>10 that group is what she is reporting.</p> <p>11 Q At week four, there was only one positive</p> <p>12 finding, correct?</p> <p>13 A Again, there was one spot that showed</p> <p>14 evidence of oxidation.</p> <p>15 Q Do you know why she didn't have a positive</p> <p>16 finding in the second and third samples, but</p> <p>17 had one the week before supposedly?</p> <p>18 A I wouldn't say supposedly. Again, we are</p> <p>19 looking at individual spots. And if you look</p> <p>20 at the SEM images, you can see that there are</p> <p>21 regions where there is degradation and then</p> <p>22 regions where there is not. So there are</p> <p>23 regions on the surface of this polypropylene</p> <p>24 that are oxidized, and there are regions that</p> <p>25 are not. And this is -- these are the number</p>	<p>1 induction at week five.</p> <p>2 At week five, we see these remarkable --</p> <p>3 we see two spots, where now we have</p> <p>4 essentially 50 percent of the carbon atoms</p> <p>5 which she was looking at that are bound to</p> <p>6 oxygen. We look at these data in week five.</p> <p>7 The first two samples -- in the first sample</p> <p>8 and the second sample, we see a dramatic</p> <p>9 increase in, so that's what --</p> <p>10 Q In the third sample, there is no increase,</p> <p>11 right?</p> <p>12 A That's a region where -- well, there is some</p> <p>13 carbonyl showing up, but that's a region</p> <p>14 that was less oxidized than the other two.</p> <p>15 That's the way I would interpret that.</p> <p>16 Q The zero means no oxidation seen, correct?</p> <p>17 A Well, I think we have to -- as Dr. Dunn has</p> <p>18 testified previously, we need to consider</p> <p>19 these two peaks together, because we are most</p> <p>20 entered in looking at the fraction of carbons</p> <p>21 that are bound to oxygen. That tells us</p> <p>22 about oxidation. So we do see some carbonyl.</p> <p>23 And there is no COOH group in that sample.</p> <p>24 And, again, it is because we are looking</p> <p>25 at different -- it depends on the spot that</p>
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<p>1 of areas that that is what she observed.</p> <p>2 Q You said you all looked at the raw data where</p> <p>3 there were these peaks and things like that.</p> <p>4 Where is that in this production?</p> <p>5 A I don't see that in her report. We have that</p> <p>6 data. I'm not sure where they are.</p> <p>7 Q I'm going to request those.</p> <p>8 A Yeah, and that's not going to be a difficult</p> <p>9 thing to provide.</p> <p>10 Q Has she done any statistical testing on that</p> <p>11 XPS?</p> <p>12 A No. And as I mentioned before, XPS is really</p> <p>13 a qualitative tool to assess the structure of</p> <p>14 the bonds. It's telling us that we see these</p> <p>15 carbon-oxygen bonds that are indicative of</p> <p>16 degradation. It is confirming the FTIR</p> <p>17 findings. We are relying on the FTIR</p> <p>18 findings for a more quantitative analysis</p> <p>19 where we will run our statistical tests.</p> <p>20 And it's because with XPS, we are looking</p> <p>21 at different spots, and we can't distinguish</p> <p>22 whether it's a degraded spot or whether it's</p> <p>23 a non-degraded spot. What the XPS data</p> <p>24 confirms is that there is regions of</p> <p>25 degradation, and we can even see evidence of</p>	<p>1 you are looking at.</p> <p>2 Q The CO, that's the carbon oxygen, the</p> <p>3 carbonyl?</p> <p>4 A The CO is a carbonyl bond.</p> <p>5 Q Right.</p> <p>6 So in the first sample, there was no</p> <p>7 positive finding of the CO bond at weeks</p> <p>8 four, five or six, correct?</p> <p>9 A That's what it says, right.</p> <p>10 Q How do you explain that finding?</p> <p>11 A Again, I would look at this as adding</p> <p>12 because these are -- you know, she is trying</p> <p>13 to separate these two peaks using a</p> <p>14 mathematical algorithm. And, you know, I</p> <p>15 think we have to consider both numbers when</p> <p>16 we talk about whether the surface is oxidized</p> <p>17 or not. Both of those types of bonds can</p> <p>18 occur on the surface. That is the way the</p> <p>19 test works.</p> <p>20 Q Even though there were, as she supposedly</p> <p>21 records, RCOOH bonding, at weeks four, five</p> <p>22 and six, there is no CO bonding. That's</p> <p>23 fair, correct?</p> <p>24 A That is what her analysis shows.</p> <p>25 Q And there is zeros at even weeks five and</p>

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<p>1 six, correct?</p> <p>2 A Again, it depends on the spot you're looking</p> <p>3 at.</p> <p>4 Q Is it true or not, though, that there is</p> <p>5 zeros at weeks five and six?</p> <p>6 A Yeah, that's what I just said.</p> <p>7 Q And these numbers are not consistently</p> <p>8 showing oxidation across all samples at the</p> <p>9 same time point either; is that correct?</p> <p>10 A That's correct. And, again, that's because</p> <p>11 of where you are looking, just like the SEM</p> <p>12 images, not all regions are degraded.</p> <p>13 Q Or it could be because of issues in the test,</p> <p>14 correct?</p> <p>15 A Unlikely.</p> <p>16 Q But that's a possibility?</p> <p>17 A It's always a possibility. I mean, it's a</p> <p>18 possibility of any test.</p> <p>19 Q Have you done any analyses on cadaveric</p> <p>20 slings?</p> <p>21 A No. Cadaveric slings in my understanding</p> <p>22 aren't made of out of polypropylene.</p> <p>23 Q I think I would agree with that.</p> <p>24 But my question is simple. Have you done</p> <p>25 any testing on cadaveric slings?</p>	<p>1 Q Have you ever investigated the</p> <p>2 biocompatibility of porcine slings?</p> <p>3 A What do you mean by biocompatibility? That's</p> <p>4 a pretty controversial word. You mean in an</p> <p>5 ISO context or -- I'm not sure what you mean.</p> <p>6 Q I thought somewhere you talk about</p> <p>7 biocompatibility.</p> <p>8 A Where do I talk about biocompatibility? I</p> <p>9 want to be very careful with that word</p> <p>10 because it has a very evolving meaning.</p> <p>11 There is an ISO 10993 biocompatibility test</p> <p>12 that measures certain characteristics of the</p> <p>13 device. But biocompatibility really can be</p> <p>14 best understood in the context of the</p> <p>15 material and where it's being implanted. I'm</p> <p>16 not sure what you're asking about is the</p> <p>17 problem.</p> <p>18 Q Have you done any analysis on cadaveric</p> <p>19 slings for incontinence? Meaning, have you</p> <p>20 searched the literature to try to understand</p> <p>21 whether they degrade, whether they remodel,</p> <p>22 anything like that?</p> <p>23 A I have looked at that some, but not -- my</p> <p>24 understanding is that there is this Burch</p> <p>25 procedure where they can use autograft, I'm</p>
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<p>1 A No. Why would I?</p> <p>2 Q I'm just asking.</p> <p>3 A Okay.</p> <p>4 Q You're reading too much into my question.</p> <p>5 A It's just this kind of came out of no where.</p> <p>6 Q Have you ever done any testing on biologic</p> <p>7 slings?</p> <p>8 MR. KUNTZ: Don't do this.</p> <p>9 MR. SNELL: I'm going to come</p> <p>10 back to it, I'm sure.</p> <p>11 BY MR. SNELL:</p> <p>12 Q Are you aware that biologic slings can</p> <p>13 degrade?</p> <p>14 A Okay. I would not use -- your terms are a</p> <p>15 little -- when you say biologic, are you</p> <p>16 talking about like the autograft or the</p> <p>17 allograft? What do you mean by biologic?</p> <p>18 Q You know like a pig sling.</p> <p>19 A You're supposed to call that a xenograft. I</p> <p>20 don't know that I would use the word degrade.</p> <p>21 I would prefer to use a word like remodel.</p> <p>22 It's reabsorbed, you know, so the old tissue</p> <p>23 in the xenograft is absorbed, and then new</p> <p>24 tissue is deposited by it. That's my</p> <p>25 understanding of what you're saying, I think.</p>	<p>1 aware of that, where they harvest autograft,</p> <p>2 There is the Lynn paper that talks about</p> <p>3 harvesting autograft and then implanting that</p> <p>4 as a sling. I'm less familiar with the</p> <p>5 allograft and xenograft models. I don't know</p> <p>6 where you would get allograft for something</p> <p>7 like this.</p> <p>8 But you're saying that there is a pig</p> <p>9 xenograft --</p> <p>10 Q Sling.</p> <p>11 A I'm not so familiar with that.</p> <p>12 Q Okay. Have you have done any research or</p> <p>13 seen any literature that specifically looks</p> <p>14 at polypropylene slings and determines that</p> <p>15 they did not degrade?</p> <p>16 A Again, I would like to be careful about this</p> <p>17 word degrade, so I'm going to answer your</p> <p>18 question as best as I can. I have seen</p> <p>19 papers that report findings that the sling</p> <p>20 does not degrade.</p> <p>21 There is a paper by Professor Dmochowski</p> <p>22 at Vanderbilt, he is a co-author on this</p> <p>23 paper where they looked at -- but they didn't</p> <p>24 use the types of techniques we're talking</p> <p>25 about. My understanding of this paper is</p>

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<p>1 degradation was assessed by a pathologist</p> <p>2 from an H&E stained section. And it's not</p> <p>3 clear to me that you would be able to see</p> <p>4 degradation with a method like this unless it</p> <p>5 were really bad.</p> <p>6 So I'm aware of those papers, and I have</p> <p>7 read them, and I have considered those views.</p> <p>8 My concern is that they don't always use</p> <p>9 these same techniques.</p> <p>10 Q What doctor was that? Was that a doctor?</p> <p>11 A Yes. He's a urologist at Vanderbilt.</p> <p>12 Q Dmochowski?</p> <p>13 A Dmochowski. That's who I'm talking about.</p> <p>14 And I think you know him.</p> <p>15 Q Any other papers?</p> <p>16 A That's the one that comes to mind. I think</p> <p>17 there are others too, but that is the one</p> <p>18 that comes to mind. I mean, there is these</p> <p>19 Nelson studies and these other papers, but,</p> <p>20 again, they're not specifically looking --</p> <p>21 they may report that there is no degradation,</p> <p>22 but when you read the paper, it's -- well,</p> <p>23 in this case, they do patient surveys.</p> <p>24 So how are you going to know that the</p> <p>25 mesh degraded if you're just talking to</p>	<p>1 supports these opinions, but it doesn't</p> <p>2 change them.</p> <p>3 So if we look at opinion three -- and we</p> <p>4 talked about this, but if we look at opinion</p> <p>5 three, the antioxidants do not eliminate</p> <p>6 degradation, and they do not guard</p> <p>7 indefinitely against oxidative -- this is --</p> <p>8 the testing is relevant to this opinion. But</p> <p>9 other than that -- again, it's the same</p> <p>10 opinion. I'm just saying that the testing</p> <p>11 further supports it. It doesn't change the</p> <p>12 opinion.</p> <p>13 Q The testing you're referring to is the</p> <p>14 testing that we've been looking at?</p> <p>15 A That we've just discussed, yeah.</p> <p>16 Q And that's pertinent to opinion number three</p> <p>17 about the antioxidants?</p> <p>18 A I would say it's really pertinent to all</p> <p>19 five, but most specifically of opinion three</p> <p>20 I would say. Opinion six, I think, is</p> <p>21 similar. I did talk in Huskey about</p> <p>22 Ethicon's internal documents -- I'm referring</p> <p>23 to oxidative degradation.</p> <p>24 Q Which document are you talking about there?</p> <p>25 A There is the Guidon study, the eight-year</p>
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<p>1 someone in a survey. So I'm aware that those</p> <p>2 papers are out there, and I have a read a</p> <p>3 number of them.</p> <p>4 MR. SNELL: We are going to mark</p> <p>5 your summary of opinions as the next exhibit.</p> <p>6 (Deposition Exhibit No. 4 was</p> <p>7 marked for identification.)</p> <p>8 BY MR. SNELL:</p> <p>9 Q So as we go through your opinions -- and just</p> <p>10 to perhaps save us a little time, these are</p> <p>11 the similar or the same opinions that you had</p> <p>12 at the Huskey case, correct?</p> <p>13 A Yes, most of them are. If it would help, I</p> <p>14 can distinguish which opinions have been</p> <p>15 modified or are different since Huskey.</p> <p>16 Q Yes, that would be great.</p> <p>17 Let me ask you to look at the exhibit we</p> <p>18 marked for your summary of opinions in</p> <p>19 Mrs. Perry's case, and tell us if the</p> <p>20 opinions have been changed or added or</p> <p>21 modified as compared to your Huskey opinion.</p> <p>22 A So I believe opinions one, and two, and</p> <p>23 three, four, five, those five opinions are</p> <p>24 very similar to Huskey. What I would say is</p> <p>25 new is the testing that we did further</p>	<p>1 explanted suture study. There is some other</p> <p>2 -- the dog study even shows evidence of</p> <p>3 degradation. Those are the two that come to</p> <p>4 mind.</p> <p>5 There is some comments in those reports</p> <p>6 about scraping off material that appeared to</p> <p>7 be degraded polypropylene on the basis of its</p> <p>8 melting point and appearance, and</p> <p>9 environmental stress cracking in the sutures.</p> <p>10 All of that was discussed in Huskey.</p> <p>11 Q In the Guidon eight-year explant suture study</p> <p>12 that you referenced, when did those findings</p> <p>13 of dyspareunia show?</p> <p>14 A When did those findings of dyspareunia -- see</p> <p>15 that. You're being cheeky now.</p> <p>16 Q Yeah.</p> <p>17 In the Guidon finger explant suture,</p> <p>18 that's the vascular graft?</p> <p>19 A That's right.</p> <p>20 Q All right. At what point did the positive</p> <p>21 findings that you relied on show up on that</p> <p>22 study?</p> <p>23 A So it was the eight-year time point where the</p> <p>24 surface cracking became -- I think there was</p> <p>25 some cracking observed at earlier time</p>

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<p>1 points, but in eight years, I remember it</p> <p>2 being very severe.</p> <p>3 Q And the dog study, at what point in time did</p> <p>4 any of those findings become significant?</p> <p>5 A I would have to look at the documents again,</p> <p>6 but my latest review of them, it was -- what</p> <p>7 I remember is the conclusion from the study</p> <p>8 is that the cracking became worse with time,</p> <p>9 up to seven years. Again, that was all</p> <p>10 discussed in Huskey.</p> <p>11 Q I didn't see that. I don't know if you</p> <p>12 focused on the timing.</p> <p>13 A Okay. Well, I just read this last night when</p> <p>14 I was preparing, and I remember some</p> <p>15 statements saying that the cracking appeared</p> <p>16 to get worse. We can pull it up if you want</p> <p>17 to talk about it.</p> <p>18 Q Yes, let's just pull it up. I just want to</p> <p>19 understand what you're talking about.</p> <p>20 It would be under reliance documents?</p> <p>21 A I believe it would be.</p> <p>22 Q Do you remember how you had it labeled?</p> <p>23 MR. KUNTZ: Do you want to ask</p> <p>24 some questions about it?</p> <p>25 MR. SNELL: Yes, just that one</p>	<p>1 point. Now, I'm looking at the seven year</p> <p>2 time point. And the conclusions I am reading</p> <p>3 here, the seven-year in vivo results</p> <p>4 generally substantiated the five-year</p> <p>5 findings, degradation in Prolene is still</p> <p>6 increasing.</p> <p>7 So the way I interpret this is from year</p> <p>8 five to year seven, the degradation is</p> <p>9 progressing, but I don't see any SEM images</p> <p>10 here.</p> <p>11 Q Do you know from that study when the cracking</p> <p>12 first appeared, besides in five years?</p> <p>13 A A few time points I have is five years and</p> <p>14 seven years is what's shown in this study.</p> <p>15 And then the fact that it got worse from year</p> <p>16 five to year seven, and that's what is</p> <p>17 reported in this study. And that's what I am</p> <p>18 relying on for this opinion.</p> <p>19 Q That study doesn't establish that the</p> <p>20 cracking was there at, say, three years?</p> <p>21 A It doesn't establish it was there at three</p> <p>22 years because there was no three-year time</p> <p>23 point.</p> <p>24 Q All you know is that at five years, two out</p> <p>25 of the overall sample had some cracking?</p>
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<p>1 question about the time point.</p> <p>2 MR. KUNTZ: You can use my copy,</p> <p>3 but I don't want it marked as an exhibit. It</p> <p>4 has highlights on it. I mean, just to speed</p> <p>5 things up.</p> <p>6 MR. SNELL: That's fine.</p> <p>7 (Off-the-record discussion.)</p> <p>8 BY MR. SNELL:</p> <p>9 Q Okay. Go ahead.</p> <p>10 A I'm just going to give you some points here.</p> <p>11 So there is -- my understanding is that this</p> <p>12 dog study was designed to be a ten-year</p> <p>13 study. There was a five-year report that was</p> <p>14 issued. In five years, two out of the seven</p> <p>15 Prolene explants revealed cracking in five</p> <p>16 years. And then there is some SEM images</p> <p>17 here that show those explants, and I can see</p> <p>18 the cracking that they're referring to in two</p> <p>19 of those explants.</p> <p>20 I would say that at least in the image I</p> <p>21 have it's difficult to tell, but it looks</p> <p>22 like there is a third one that might be</p> <p>23 showing some evidence as well. This is what</p> <p>24 I can see in these micrographs that are not</p> <p>25 terribly clear. That was the five-year time</p>	<p>1 A That's right.</p> <p>2 Q So you were looking at your list of opinions,</p> <p>3 and you had talked about number six. And</p> <p>4 number seven?</p> <p>5 A So number seven, Ethicon ignored the warning</p> <p>6 contained in the MSDS for the polypropylene</p> <p>7 use in its products. It says the strong</p> <p>8 oxidizing agents, like peroxides, are</p> <p>9 incompatible with the polypropylene to the</p> <p>10 detriment of patients implanted with the</p> <p>11 mesh. So the MSDS warns that polypropylene</p> <p>12 is sensitive to oxidation.</p> <p>13 Again, our testing plays into this</p> <p>14 because our testing has shown that even with</p> <p>15 the antioxidants, it can oxidize. They don't</p> <p>16 protect it forever, as I've wrote in opinion</p> <p>17 three. And this is a detriment to patients</p> <p>18 implanted with the mesh for two reasons.</p> <p>19 One is, we've seen that oxidation</p> <p>20 degradation can lead to embrittlement, pain,</p> <p>21 and complications, as I have testified, with</p> <p>22 Costello and Clave and Huskey in previous</p> <p>23 testimony, and it increases the risk. It's</p> <p>24 unpredictable, so it increases the risk to</p> <p>25 the patients. It's a risk that they have to</p>

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<p>1 live with for their entire lives because the 2 device is there. 3 And as long as it's there, it's going to 4 be -- this reaction is ongoing. That's 5 opinion five. And it's important that the 6 antioxidants don't protect it forever. 7 Q That's basically the same as what you 8 expressed in Huskey? 9 A I believe it is. I just wanted to qualify 10 that I do believe that the testing data has 11 some impact on that opinion, and we've been 12 discussing that. But it's a similar opinion 13 to that held in Huskey. 14 Q What about number eight? 15 A Number eight, I think, is also similar to 16 Huskey. 17 Q In Huskey, as I recall it -- I mean, the 18 primary studies and documents that you 19 referred to and relied upon were the dog 20 study, the vascular suture graft study, 21 Clave, Costello? 22 A Yes. 23 Q The other one you mentioned today, Liebert, 24 is that another one that is important to your 25 opinions?</p>	<p>1 provide evidence of oxidation and degradation 2 and conclude that that contributed to the 3 embrittlement of the mesh. That could be 4 done. I did not do that in this case. I 5 didn't have the materials, but I don't want 6 to -- I would say from -- I don't -- maybe to 7 give you a better answer, I am not reviewing 8 medical records and -- 9 Q You're not doing a differential diagnoses and 10 drawing causal relationship inferences? 11 A Not in this case, no. 12 Q Nor in general, correct? 13 A I have testified that -- again, I saw 14 evidence of myeloperoxidase, which was 15 evidenced to me that these oxidative 16 processes are ongoing. That would lead to 17 changes in the polypropylene. So in terms of 18 -- you had a question? 19 Q The myeloperoxidase is not something you have 20 done on an Ethicon mesh? 21 A That's correct. 22 Q It's not something you have done on an 23 explant from an Ethicon patient to your 24 knowledge? 25 A To my knowledge. It may be in</p>
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<p>1 A Yes, all of those studies that we've 2 discussed. 3 Q Okay. 4 MR. KUNTZ: I'm just going to 5 object. We have provided everything to you 6 he has relied on. It's not a memory test to 7 point out every single document, but I think 8 I understand your question. 9 A I testified that on those at Huskey, and my 10 opinion has not changed in that regard. 11 BY MR. SNELL: 12 Q And so I'm not going to recover those things 13 with you. 14 A That would be great. 15 Q You're not offering any medical or clinical 16 opinions with regard to Mrs. Perry at all; is 17 that correct? 18 A That's correct. 19 Q That would be totally outside your expertise, 20 correct? 21 A Medical and -- 22 Q Clinical? 23 A Medical and clinical? Just for the record, I 24 would not say it would be outside my 25 expertise to test the explanted mesh and</p>	<p>1 Dr. Iakovlev's, but I don't know. 2 Q And you understand that doctors are the ones 3 who actually do differential diagnoses and 4 draw conclusions about what complications 5 patients have? 6 A Could you explain differential diagnosis, 7 please? 8 Q Let me ask you, do you know what a 9 differential diagnosis is? 10 A Not precisely, I don't think. So I suppose I 11 wouldn't do that. I mean, it sounds like a 12 medical term to me. 13 Q Opinion number nine, explain that opinion to 14 me. Clearly, this is different. 15 A So after reviewing all of the Ethicon 16 documents and some published papers, my 17 conclusion was that this TVT Abbrevio mesh is 18 stiffer. There are several e-mails from 19 inventors of the mesh, such as Dr. Della 20 Valle, Dr. Nelson, that observed this 21 increase in stiffness, complained about an 22 increase in complications, asserted that this 23 mesh was different, and you could not rely 24 upon TVT machine-cut mesh data to support the 25 notion that TVT Abbrevio is the same.</p>

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<p>1 I reviewed mechanical testing done by 2 Ethicon, and an effort by Dr. Kammerer, I 3 believe, who is a fellow at Ethicon, who 4 basically replotted some of those data and 5 argued from Lynn that the mesh is subject to 6 the very small forces in this environment. 7 And when you compare over that very small 8 force range, he reported that the elongation, 9 the mechanical properties are the same. 10 I do not think this is a good way to 11 approach the problem. I think you would have 12 to consider as in the paper by Dietz, where 13 he went out to 80 percent, something -- okay. 14 So with the original Ethicon testing, they 15 went to 14 or 15-percent elongation. The 16 Dietz paper went out to maybe 80-percent 17 elongation. And at those higher elongations, 18 there are significant differences, stiffness 19 of TVT machine-cut and TVT laser-cut. 20 Dr. Kammerer only plotted the data over a 21 range of up to about a 4-percent strain 22 elongation, and that was just a very limited 23 range. He concluded that they were similar, 24 but I questioned the physiological relevance 25 of his approach in asserting that Lynn could</p>	<p>1 the decision-making process, not -- I did not 2 test these meshes mechanically. I'm making 3 this opinion on the basis of Ethicon 4 documents where they chose -- they 5 deliberately selected different ranges over 6 which to view the mechanical data. That's 7 what I'm questioning. 8 Q Well, I'm going to get to that. My focus is 9 on the e-mails. 10 Basically, what you did is you looked at 11 some e-mails that some people wrote, and you 12 adopted what they said, correct? 13 A Well, what do you mean I adopted what they 14 said? 15 Q Did you assume what was written on the paper 16 was accurate or true? 17 MR. KUNTZ: I'm just going to 18 object. 19 A I'm still not getting it. I mean, there was 20 statements by these surgeons that said it's 21 not the same. 22 BY MR. SNELL: 23 Q Okay. This is what I am just asking -- maybe 24 I'm making it too complex. 25 A Okay. I'm just not getting something.</p>
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<p>1 be used to support that assumption. That's 2 my opinion. 3 So the mesh, I believe, is stiffer. And 4 the decision was made to use the TVT 5 machine-cut data that is for the laser-cut 6 product even though it was different. That's 7 my opinion on number nine. 8 Q So you looked at the e-mails where 9 Dr. Della Valle or others may have written in 10 comments about the mesh being stiffer, 11 correct? 12 A I reviewed those e-mails, yeah. 13 Q So you read those the e-mails, and you 14 basically took as what they said to be as 15 true, right? 16 A I read as much as I could read. I read a lot 17 of documents. 18 Q How about this, what independent testing did 19 you do, if any, to confirm or not confirm 20 the supposed higher level of stiffness of 21 the mesh? 22 A Well, honestly I felt like I didn't need to 23 do independent testing. This is Ethicon data 24 that they relied on to make decisions. 25 That's what I'm criticizing. I'm criticizing</p>	<p>1 Q You saw some statements in an e-mail? 2 A Yes. 3 Q And you read them and what they meant to you, 4 right? 5 A Yeah. It seemed like a straight forward 6 statement. And I read it and that's what it 7 said, so I just -- 8 Q You didn't apply any further analysis to this 9 statement? 10 A What further analysis would I have applied? 11 It is just what it said. There were multiple 12 e-mails and there was an e-mail chain. I 13 read the question, and I read the response, 14 and I -- I mean, I did my best to review it, 15 but some of these comments were rather blunt 16 and direct, so it was -- 17 Q So you interpreted the statements without 18 doing any testing of their veracity or -- of 19 the points? 20 A I don't know how to test their veracity. It 21 just -- I mean, there were multiple 22 statements and there were multiple e-mails 23 that seemed to -- among Ethicon employees 24 that addressed this as a concern, so it just 25 wasn't one e-mail. It was -- there seemed to</p>

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<p>1 be many documents posing the question is TVT 2 machine-cut the same as TVT laser-cut Abbrevio 3 -- laser-cut versus the machine-cut. 4 There were numerous opinions and 5 documents going back and forth. Many were 6 questioning this decision. Others were 7 promoting it. There was -- it looked like a 8 fair amount of descension until Dr. Kammerer 9 did his analysis, and then what appeared to 10 me is that the decision was taken that these 11 products are the same. 12 So I read a lot of documents to form 13 this. I mean, if there is another one you 14 would like me to read, I would be happy to 15 read it. That's why I'm here. But this is 16 what I read, and this is what I saw, and this 17 is the opinion I came to. 18 Q I mean, these were basically e-mails written 19 by other people who wrote into the company. 20 And that's what you looked at, correct? 21 A Yes, but some were internally e-mails between 22 -- conversations between Ethicon employees 23 and Europe and North America and -- 24 Q Fair enough. 25 These are people writing e-mails to other</p>	<p>1 A That's the difference -- to my understanding, 2 that's the only difference in how they are 3 manufactured, but that could introduce 4 differences -- well, okay. 5 Q But they are the same in that respect, 6 correct? 7 A The same in what respect? 8 Q That they are the same up until the point 9 when they decide to cut the edges of the mesh 10 either mechanically or they do it with 11 laser, correct? 12 A I understand, yeah. 13 Q Is that correct? 14 A I believe so. I mean, I don't have the 15 details of how these are -- 16 Q So if we have two pieces of mesh, this is 17 mechanical, this is laser, is there any 18 difference in the mesh that is running down 19 the middle? 20 A I don't know. That has not been tested. All 21 I can say is that they are cut differently. 22 What affect that has on the mesh in the 23 middle, I don't know that that's been tested. 24 Q They are knitted the same, right? 25 A Yeah, but that cutting operation could change</p>
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<p>1 people, correct? 2 A Yes. 3 Q The laser-cut and the mechanical cut mesh, 4 they are the same mesh, correct? 5 MR. KUNTZ: Objection. 6 A I would say they are cut from the same 7 Prolene mesh, but I would not say that they 8 are the same mesh. One has cut edges with a 9 machine, the other has a cut with a laser. 10 That's not the same to me. But if you want 11 to say they're prepared from the same source 12 mesh, I believe that's correct. 13 BY MR. SNELL: 14 Q Both of the meshes are made of the same 15 Prolene polypropylene, correct? 16 A That's my understanding. 17 Q And it's the same mesh that goes through all 18 of the same extrusion and manufacturing 19 processes up until the point when it's cut to 20 your understanding, correct? 21 A That's my understanding. 22 Q Right. 23 The only difference is the edges of the 24 strip of tape, one is cut mechanically and 25 one is cut with a laser, correct?</p>	<p>1 something. I just don't know and it's not 2 been looked at. 3 Q Well, Dr. Kammerer looked at it, right? 4 A No. Dr. Kammerer, I don't believe he 5 actually did any testing. I believe Dr. 6 Kammerer took data from previous experiments 7 and replotted them over a different range of 8 elongation. That's what I believe he did 9 from the documents I saw. 10 I didn't see -- all I saw in his report 11 was that he noted that he was using data from 12 other reports. I didn't see like he actually 13 did do measurements. That was my 14 understanding. 15 Q The elongation of the mesh, the 16 mechanically-cut and the laser-cut, were the 17 same at out to I believe it was 5 percent. 18 Do you have the document? 19 A It would help if we had the document. I was 20 going on my memory. I believe it was 4 21 percent maybe. It was not very many. I 22 believe it was 4 percent. It would help if 23 we had it. I don't know if it's on the disk 24 or, I mean, how easy it would be to find. 25 Q It will be on there. I'm sure if you'd look</p>

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<p>1 at it, it's on there.</p> <p>2 MR. KUNTZ: What are you looking</p> <p>3 for again?</p> <p>4 MR. SNELL: Kammerer's paper,</p> <p>5 the elongation testing.</p> <p>6 MR. KUNTZ: Which one?</p> <p>7 MR. SNELL: The analysis he did</p> <p>8 on elongation of the laser-cut versus the</p> <p>9 mechanical-cut. I want him to be able to</p> <p>10 look at it.</p> <p>11 (Off-the-record discussion.)</p> <p>12 BY MR. SNELL:</p> <p>13 Q Have you ever tested the forces in the</p> <p>14 pelvis?</p> <p>15 A No, I have not.</p> <p>16 Q What is your basis for saying that the</p> <p>17 reliance on the Lynn period paper is wrong?</p> <p>18 A Okay. So there is another -- okay. There is</p> <p>19 another e-mail by Dr. Kammerer, where he</p> <p>20 comments that the elongation on the mesh</p> <p>21 could be as high as 50 percent when it is</p> <p>22 implanted. And, obviously, if the mesh is</p> <p>23 elongated when it's implanted, that's going</p> <p>24 to move you down the force-distance curve.</p> <p>25 And the other point about Lynn is that</p>	<p>1 Does that make sense?</p> <p>2 Q This is the sling under the urethra, correct</p> <p>3 A Yeah.</p> <p>4 Q Do you know the size of the urethra?</p> <p>5 A Probably pretty small.</p> <p>6 Q So that low number, that small number -- do</p> <p>7 you understand that? Do you know whether</p> <p>8 that is consistent or inconsistent with basic</p> <p>9 anatomy and physiology of the urethra, in the</p> <p>10 support structures lying underneath the</p> <p>11 urethra?</p> <p>12 A It just seems to me that the sling in that</p> <p>13 study is different from the slings that are</p> <p>14 being used as the TVT. It's placed</p> <p>15 differently. I just don't know that you can</p> <p>16 make that same extrapolation, that the force</p> <p>17 on that autograft sling when somebody coughs</p> <p>18 is the same. It just seems --</p> <p>19 Q Do you know that you can't? I mean, have you</p> <p>20 done any testing or done any research that</p> <p>21 ever shows that one cannot do that?</p> <p>22 MR. KUNTZ: Objection. From</p> <p>23 what he has already said? From what Kammerer</p> <p>24 has already said? I just want to make sure</p> <p>25 we're clear.</p>
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<p>1 what Lynn was really measuring was a</p> <p>2 differential force. So Lynn was measuring --</p> <p>3 so the patients were grafted with this what</p> <p>4 looked like the autograft fascia sling, and</p> <p>5 he was measuring the force when they cough</p> <p>6 with a full or empty bladder. That is a</p> <p>7 differential force. You don't know what the</p> <p>8 initial force or tension of the elongation of</p> <p>9 that sling was.</p> <p>10 And the differential forces that he was</p> <p>11 measuring were so small. They are something</p> <p>12 in the range of .1 to .2 pounds. I mean,</p> <p>13 that's like taking the meat patty from a</p> <p>14 junior cheeseburger and hanging it on -- I</p> <p>15 mean, we are talking forces that are really</p> <p>16 small. And that's a differential force on a</p> <p>17 sling when somebody coughs.</p> <p>18 It just doesn't seem very plausible to</p> <p>19 me. It's a very small force. If the sling</p> <p>20 is elongated up to 50 percent, when it's --</p> <p>21 then it's got some strain, and you don't know</p> <p>22 what that is. But that's going to make the</p> <p>23 stiffness higher if you're moving down that</p> <p>24 force-stiffness curve. That's what I'm</p> <p>25 saying.</p>	<p>1 MR. SNELL: No, I'm asking him.</p> <p>2 He says he doesn't know. Well, what I'm</p> <p>3 asking you is --</p> <p>4 MR. KUNTZ: He just referred to</p> <p>5 Ethicon's own document, where Gene Kammerer</p> <p>6 said it was different. Besides that?</p> <p>7 MR. SNELL: No, he didn't.</p> <p>8 MR. KUNTZ: Yeah, he did. He</p> <p>9 said his e-mail -- yes, he said exactly that.</p> <p>10 And now you're trying to say that he didn't.</p> <p>11 A I'm saying that Dr. Kammerer said that when</p> <p>12 you implant a sling, it can elongate as much</p> <p>13 as 50 percent. And 4 percent -- I mean, I've</p> <p>14 seen these slings. For 4 percent, that's</p> <p>15 like -- 4-percent elongation is like folding</p> <p>16 it out of the box. I mean, it's such a small</p> <p>17 amount.</p> <p>18 When you install it, it could be 40 or</p> <p>19 50-percent strain, and that moves you much</p> <p>20 further down that stress-strain curve where</p> <p>21 these materials become very, very different.</p> <p>22 That is Dr. Kammerer's email. And then he</p> <p>23 takes this paper from Dr. Lynn that says,</p> <p>24 well, actually, the differential -- he</p> <p>25 doesn't even call it a differential force, so</p>

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<p>1 that's what it was, because he doesn't know</p> <p>2 the initial force on that sling.</p> <p>3 He just knows that when somebody coughs</p> <p>4 and exerts an additional force, that force</p> <p>5 was in the range of half a newton.</p> <p>6 BY MR. SNELL:</p> <p>7 Q How do you know what Dr. Kammerer knows?</p> <p>8 A Well, that's what he wrote.</p> <p>9 Q Well, you just testified that he didn't know</p> <p>10 something. How do you know that?</p> <p>11 A What did I say? I don't know what I said he</p> <p>12 didn't know. I don't know. He said that</p> <p>13 when you implant the sling, it can extend,</p> <p>14 it can elongate as much as 50 percent. Well,</p> <p>15 that's a lot more than 4 percent.</p> <p>16 Q Do you know what that was in the context of</p> <p>17 and what type of testing that was in the</p> <p>18 context of?</p> <p>19 A In my understanding of reading that e-mail,</p> <p>20 that was in the context of the procedure, of</p> <p>21 implanting the sling.</p> <p>22 Q The 50-percent elongation testing you've seen</p> <p>23 done, they didn't even have the sheath on the</p> <p>24 mesh; is that correct? Do you know what I'm</p> <p>25 talking about? Have you seen 50-percent</p>	<p>1 That's what he says in the report.</p> <p>2 I mean, I can read from it if you want</p> <p>3 to, but that's to me what he said. He used</p> <p>4 Lynn to justify that half a newton of force.</p> <p>5 Q Have you have read Dr. Kammerer's deposition?</p> <p>6 A I can't remember. I don't know. I don't</p> <p>7 remember anything specific from his</p> <p>8 deposition.</p> <p>9 Well, I would be interested to --</p> <p>10 Q You would be interested to what?</p> <p>11 A No, I'm just --</p> <p>12 MR. KUNTZ: I would be</p> <p>13 interested why we got that e-mail after his</p> <p>14 depo, but we can take that up with somebody</p> <p>15 else.</p> <p>16 BY MR. SNELL:</p> <p>17 Q Item number ten, I think this was something</p> <p>18 that was in Huskey, but you tell me if I'm</p> <p>19 wrong.</p> <p>20 A There is an element to that. What's new here</p> <p>21 would be referring to this laser-cut versus</p> <p>22 machine-cut. I don't believe -- to my</p> <p>23 knowledge, the studies that were done were</p> <p>24 this mechanical testing that I was referring</p> <p>25 to. There was a 14-day rabbit study where</p>
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<p>1 elongation testing?</p> <p>2 A I'm not talking about testing. In</p> <p>3 Dr. Kammerer's e-mail, he talked about with</p> <p>4 the meshes and the procedures he's observed,</p> <p>5 the mesh can elongate up to 50 percent. That</p> <p>6 was, I think, the language that he used. So</p> <p>7 that tells me when it is being implanted,</p> <p>8 it's elongating. It's no longer -- it's not</p> <p>9 4 percent. I mean, he is saying it could be</p> <p>10 up to 50 percent. That is a much bigger</p> <p>11 number than meaning 4. So I'm questioning</p> <p>12 how he got this -- he basically took this</p> <p>13 number of 4-percent strain, which is very</p> <p>14 low, so he could argue that -- that's what it</p> <p>15 looks like, that he could argue that over</p> <p>16 that very small strain that these meshes are,</p> <p>17 in fact, the same.</p> <p>18 Q That is your inference of what was going</p> <p>19 through his head?</p> <p>20 A That's what he said in this document. He</p> <p>21 puts that number for Lynn out, and then he</p> <p>22 goes to that stress strain curve, and he</p> <p>23 plotted the data over that range that he felt</p> <p>24 was physiologically relevant on the basis of</p> <p>25 the findings from Lynn. That's what he did.</p>	<p>1 they were measuring the infiltration, and</p> <p>2 they were measuring pull-out strength, but it</p> <p>3 was a very short time point, only 14 days.</p> <p>4 And then there were e-mails from some of</p> <p>5 these clinicians saying that we can't -- you</p> <p>6 just can't use TVT machine-cut clinical data</p> <p>7 to support TVT machine-cut, the notion that</p> <p>8 the TVT laser-cut would perform the same,</p> <p>9 because the meshes are different. And I</p> <p>10 don't think they did enough testing to</p> <p>11 establish whether they were different or not.</p> <p>12 I would have liked to have seen more testing</p> <p>13 to establish that fact.</p> <p>14 Q What testing was done?</p> <p>15 A What testing was done?</p> <p>16 Q That's you're aware of.</p> <p>17 Well, let me back up.</p> <p>18 A Okay.</p> <p>19 Q Did you do a PubMed or any other kind of</p> <p>20 search to see what clinical literature there</p> <p>21 was on the Abbrevio or laser-cut and</p> <p>22 mechanical-cut meshes?</p> <p>23 A I think there is some study on TVTS, which is</p> <p>24 a -- but that product is off the market now.</p> <p>25 I was relying heavily on these Ethicon</p>

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<p>1 documents, what they did, and the conclusions</p> <p>2 that they drew from the testing that they</p> <p>3 did. And I just thought that it wasn't -- it</p> <p>4 wasn't enough. It wasn't convincing from the</p> <p>5 way that the whole Kammerer conclusions were</p> <p>6 drawn to a 14-day rabbit test. There should</p> <p>7 have been more preclinical testing.</p> <p>8 I mean, why did they not file a new</p> <p>9 510(k)? That could have been a relatively</p> <p>10 straight forward thing to do.</p> <p>11 But to my knowledge, they didn't even</p> <p>12 file a new 510(k) for the laser-cut mesh.</p> <p>13 They just said it's the same without really</p> <p>14 enough testing to reach that conclusion.</p> <p>15 There was a process change that was just made</p> <p>16 and never really validated. That's what that</p> <p>17 opinion was saying.</p> <p>18 Q The e-mails from the clinicians, that's the</p> <p>19 same ones we talked with about with regard to</p> <p>20 opinion number nine?</p> <p>21 A Yeah.</p> <p>22 Q And the 14-day rabbit study?</p> <p>23 A That's what I remember. I think there was a</p> <p>24 14-day rabbit study.</p> <p>25 Q Do you know if that is the type of study that</p>	<p>1 offer an opinion that a 510(k) should have</p> <p>2 been filed for laser-cut? Because if you</p> <p>3 are, I want you to tell me --</p> <p>4 A I know what you want me to tell you.</p> <p>5 Q -- the regulations, and I want you to tell me</p> <p>6 exactly what documents they should have</p> <p>7 looked at. I want you to basically sit there</p> <p>8 and be a regulatory expert.</p> <p>9 A I get it.</p> <p>10 MR. KUNTZ: He will not be</p> <p>11 giving that opinion.</p> <p>12 BY MR. SNELL:</p> <p>13 Q Can you just tell me you're not going to give</p> <p>14 that opinion and then I can move on?</p> <p>15 A I'm upset about what was done. But so we can</p> <p>16 move on, I'm not going to give that opinion</p> <p>17 as a regulatory expert. There were just</p> <p>18 things that concerned me, but I'm not going</p> <p>19 -- okay. I will retract that.</p> <p>20 MR. SNELL: Jeff, he is not</p> <p>21 going to get up at trial --</p> <p>22 MR. KUNTZ: He's not going to</p> <p>23 give a 510(k).</p> <p>24 A I'm not giving a 510(k) opinion.</p> <p>25 MR. KUNTZ: That's what you want</p>
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<p>1 is normally done in the industry to assess</p> <p>2 pull-out force?</p> <p>3 A That was my understanding.</p> <p>4 Q Have you have ever conducted that type of</p> <p>5 study?</p> <p>6 A I have not. And I think that answers one</p> <p>7 question about pull-out force, but I don't</p> <p>8 know that that addresses his question of</p> <p>9 differences in stiffness between the mesh.</p> <p>10 And then these clinicians are saying that</p> <p>11 they are seeing more complications. So there</p> <p>12 were clinical warnings coming back that this</p> <p>13 -- that something seems different here.</p> <p>14 Q Are you a regulatory expert, such that you</p> <p>15 can cite to any regulations right now that</p> <p>16 say that Ethicon should have filed a 510(k)</p> <p>17 specific to laser-cut mesh?</p> <p>18 A I'm not -- I have a working knowledge of FDA</p> <p>19 approaches.</p> <p>20 Q If you're going to offer an opinion about a</p> <p>21 510(k) --</p> <p>22 A Let me think about it for a minute. I know</p> <p>23 where you are going with this. I just --</p> <p>24 Let's see if we can work through this.</p> <p>25 Q Well, my question is, are you going to try to</p>	<p>1 to know.</p> <p>2 A I'm not giving a 510k opinion.</p> <p>3 BY MR. SNELL:</p> <p>4 Q Because that's a whole other issue.</p> <p>5 A I know.</p> <p>6 Q There is nothing in your disclosures that say</p> <p>7 he is a regulatory expert and he's talking</p> <p>8 510(k)'s.</p> <p>9 A I just have enough knowledge of this that I</p> <p>10 saw things that disturbed me, but I'm not</p> <p>11 going to give that opinion as a 510(k)</p> <p>12 expert. I will stick to what I told you. I</p> <p>13 will reign myself in. You are provoking me a</p> <p>14 little bit. I'm not frustrated. I'm just --</p> <p>15 Q You know what they say, some knowledge is</p> <p>16 dangerous.</p> <p>17 A I'm going to stay within the scope of my</p> <p>18 opinions that are written here.</p> <p>19 Q Thank you. I would like that.</p> <p>20 Okay. Are there specific scientific</p> <p>21 studies that Ethicon should have done that</p> <p>22 you are going to say would have produced some</p> <p>23 type of clinically or statistically</p> <p>24 significant difference as between the meshes?</p> <p>25 A I would have liked to see a longer term</p>

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<p>1 implantation test than just 14 days. I think</p> <p>2 if there were differences in stiffness, you</p> <p>3 might have seen it in 90 days, but even</p> <p>4 longer periods would have been -- this mesh</p> <p>5 could have been tested in preclinical models</p> <p>6 more relevant to the vaginal wall. So there</p> <p>7 is something new in my reliance materials.</p> <p>8 There is an abstract by Deprest,</p> <p>9 D-E-P-R-E-S-T. That was published in 2013.</p> <p>10 It's in the reliance materials, where they</p> <p>11 had a large animal model where they compared</p> <p>12 mesh in the abdominal wall to mesh in the</p> <p>13 vaginal wall, and they saw eightfold more</p> <p>14 contraction in the vaginal wall.</p> <p>15 So I think these studies could have been</p> <p>16 done by Ethicon to assess these differences.</p> <p>17 I think they could have interpreted their</p> <p>18 own mechanical data more conservatively. We</p> <p>19 already discussed that, so I don't want to</p> <p>20 bring that up again, but those are the</p> <p>21 studies. But more preclinical studies and a</p> <p>22 more thoughtful evaluation of their own</p> <p>23 mechanical data is what I would say.</p> <p>24 Q You're not saying that Gene Kammerer, who has</p> <p>25 got 40 years of experience, is incompetent,</p>	<p>1 model. I don't know.</p> <p>2 Q Would it surprise you to learn that laser-cut</p> <p>3 mesh has been tested in sheep?</p> <p>4 A In what model?</p> <p>5 Q The sheep model.</p> <p>6 A You mean on a wall model? On a subcu model?</p> <p>7 Where in the sheep was it tested?</p> <p>8 Q I guess my question is, would it surprise you</p> <p>9 if you learned that it was done?</p> <p>10 A Would it surprise me? I know that there was</p> <p>11 a lot of testing done. I wasn't aware of the</p> <p>12 study that tested in the vaginal wall. If</p> <p>13 it's a subcu test, then, again, that's a</p> <p>14 different environment. The interesting</p> <p>15 aspect of the Deprest study to me was that</p> <p>16 they looked at differences -- which they</p> <p>17 asked the question, is it different in the</p> <p>18 abdominal wall versus the vaginal wall.</p> <p>19 And I haven't seen a document that -- I</p> <p>20 mean, I would be happy to look at it if</p> <p>21 you've got one, but I haven't seen that.</p> <p>22 Q This study by Deprest, how big of a size of a</p> <p>23 mesh was implanted? Do you know?</p> <p>24 A I can't remember the details from that. It's</p> <p>25 in the abstract. I don't know.</p>
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<p>1 you just disagree with -- let me just finish.</p> <p>2 You're not saying he is incompetent, you just</p> <p>3 disagree with what he did?</p> <p>4 A He might be too confident. What he did was</p> <p>5 -- I don't like it. I don't like the way</p> <p>6 that he handled the mechanical data to say</p> <p>7 that everything was the same. I think that</p> <p>8 was a flawed approach. I'm not saying he is</p> <p>9 incompetent. I don't like the way he</p> <p>10 approached that problem. I shouldn't say</p> <p>11 don't like. I disagree with it.</p> <p>12 Q But you have not conducted any independent</p> <p>13 testing or analyses that would show what he</p> <p>14 did was incorrect?</p> <p>15 A I have not done any other testing. I was</p> <p>16 relying on Ethicon documents at the time of</p> <p>17 testing.</p> <p>18 Q This Deprest 2013 paper, what type of animal</p> <p>19 model was that? Was that a pig?</p> <p>20 A It was a sheep. It is an abstract, I</p> <p>21 believe, in the IUGA meeting in 2013. It's</p> <p>22 in the reliance materials. That's new.</p> <p>23 Q Do you know whether the laser-cut mesh has</p> <p>24 ever been subjected to testing in a sheep?</p> <p>25 A I don't know if there was testing in that</p>	<p>1 Q Do you know how they implanted it in the</p> <p>2 vaginal wall?</p> <p>3 A I can't remember how they did that.</p> <p>4 Q It wasn't a sling put between the vagina and</p> <p>5 the urethra?</p> <p>6 A I don't believe it was a sling. I believe it</p> <p>7 was more -- I just would have to look at it</p> <p>8 again to remember it, but I don't believe it</p> <p>9 was a sling. I think they implanted the</p> <p>10 piece of mesh, but I can't remember the</p> <p>11 details of how they did that.</p> <p>12 Q Do you know when was a sheep model where</p> <p>13 implantation in the sheep's vagina was first</p> <p>14 perfected?</p> <p>15 A I really don't understand. You mean as a</p> <p>16 sling or you mean as like an implant? I'm</p> <p>17 not sure what you mean.</p> <p>18 Q As a model. Usually animal models, right,</p> <p>19 you just don't come up with some theory and</p> <p>20 do the model. Don't you have to test models</p> <p>21 before you actually do them?</p> <p>22 A Yeah. I mean, I work with colleagues where</p> <p>23 we design new models for bone healing.</p> <p>24 Q Is there a way to validate models? I guess</p> <p>25 that's what -- I'm kind of getting towards,</p>

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<p>1 that area.</p> <p>2 A Yes. So if you want to validate a functional</p> <p>3 model, that's a different question. I think</p> <p>4 what they did in this study is they just</p> <p>5 implanted it adjacent to the tissue. I don't</p> <p>6 think it was intended to be a functional</p> <p>7 sling model.</p> <p>8 They were just asking the question, well,</p> <p>9 if I implant it here at the hernia abdominal</p> <p>10 wall versus here in the vaginal wall, do I</p> <p>11 see differences in cellular infiltration and</p> <p>12 contraction and those kinds -- it wasn't a --</p> <p>13 this abdominal wall model has been around for</p> <p>14 a while, right. So I think what they did</p> <p>15 that was different is they implanted it in</p> <p>16 the vaginal wall as well.</p> <p>17 Q It wasn't validated, though, as between the</p> <p>18 vaginal wall of the sheep and the abdominal</p> <p>19 wall of the sheep?</p> <p>20 A I don't know what you mean by validated.</p> <p>21 When I think of validation, that's like a</p> <p>22 functional model that you have to validate to</p> <p>23 make, so if you wanted to make a sheep sling</p> <p>24 model, you would have to validate that. I</p> <p>25 understand that, but I don't think that that</p>	<p>1 what I've found. I haven't -- well, I have</p> <p>2 looked. That's what I know right now.</p> <p>3 Q So have we discussed ten?</p> <p>4 A I don't have anything to add to ten.</p> <p>5 Q And 11 is similar to number ten -- or how is</p> <p>6 that different from anything you talked about</p> <p>7 in Huskey?</p> <p>8 A Let me read it for a minute.</p> <p>9 Q Sure.</p> <p>10 A I think the point in 11 is that when I say</p> <p>11 did not consider -- I think there is a lot of</p> <p>12 overlap with Huskey. They do not consider</p> <p>13 principles of biomaterial science by not</p> <p>14 testing it in an oxidative environment using</p> <p>15 a known test that was known since the early</p> <p>16 90's. Even though they knew and from their</p> <p>17 own studies, they saw evidence of oxidation</p> <p>18 and degradation, they never tested it.</p> <p>19 So to me, biomaterial science, if I know</p> <p>20 something is susceptible to oxidation, I need</p> <p>21 to test that and assess it. And I guess what</p> <p>22 would be new here is that, you know, we have</p> <p>23 tested that. In one exemplar of TVT mesh, we</p> <p>24 found that it can't oxidize. And that test</p> <p>25 could have been done by Ethicon. That is</p>
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<p>1 is what they did.</p> <p>2 Q This wasn't a validated sheep model study?</p> <p>3 A I would say it wasn't a validated sling</p> <p>4 model. They weren't modeling the sling in</p> <p>5 the sheep and trying to draw some conclusion</p> <p>6 about how the sling would act in a human. I</p> <p>7 think they were just asking a question, how</p> <p>8 would this mesh infiltrate in these two</p> <p>9 different environments. That's what that</p> <p>10 model was, which I think is a legitimate</p> <p>11 thing to do.</p> <p>12 People have been implanting -- there is a</p> <p>13 number of rat abdominal wall models in other</p> <p>14 rodents and large animals. I don't think</p> <p>15 that is a -- I think that is a good approach.</p> <p>16 Q Have you ever seen it done before,</p> <p>17 implantation of mesh in a sheep or a large</p> <p>18 animal's vagina?</p> <p>19 A That's the first I have seen it, but there</p> <p>20 may be other studies.</p> <p>21 Q Did you do any investigation to see whether</p> <p>22 the findings were consistent or inconsistent</p> <p>23 with other testing or whether anyone had</p> <p>24 tried to do that before?</p> <p>25 A I have looked for other studies and that's</p>	<p>1 what I'm saying in 11 that is new.</p> <p>2 Q You're saying that test could have been done</p> <p>3 by Ethicon?</p> <p>4 A Yes.</p> <p>5 Q But somebody at Ethicon would actually have</p> <p>6 to believe that this cobalt study that you</p> <p>7 referenced and the solutions are what</p> <p>8 actually occurs from macrophages at an</p> <p>9 unknown concentration in the body, correct?</p> <p>10 MR. KUNTZ: Objection.</p> <p>11 A Yes. And there is some well-trained</p> <p>12 scientists at Ethicon. Those papers have</p> <p>13 been cited dozens of times and are well</p> <p>14 established in the field. They are well</p> <p>15 known in the field. Those papers were</p> <p>16 instrumental in discovering the problem of</p> <p>17 the instability of polyether urethane</p> <p>18 catheter leads, that these leads would</p> <p>19 oxidize, degrade, and in some cases fail.</p> <p>20 Those products were withdrawn from the</p> <p>21 market.</p> <p>22 So if I were at Ethicon, and I knew that</p> <p>23 story, I would be very worried about this,</p> <p>24 because it's the same type of problem, a</p> <p>25 chemical attack. It's just an environmental</p>

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<p>1 stress cracking problem, where you have an 2 oxidative environment and materials sensitive 3 to oxidation and mechanical forces. All of 4 those can lead to this environmental stress 5 cracking in device failure. 6 So if I were at Ethicon and I knew of 7 those problems with those urethane catheter 8 leads, one of the first things I would have 9 done is tested these meshes in this oxidative 10 environment so I would know. 11 BY MR. SNELL: 12 Q The urethane catheters, were those Ethicon 13 products? 14 A No. But a good biomaterials scientist 15 recognizes that these are two polymers that 16 are sensitive to oxidation. And I would at 17 least want to know -- I would want to know, 18 does it degrade, does it oxidize, does it 19 degrade. I think you have to ask that 20 question when you're designing a biomedical 21 device, what's the material made of and is 22 that a problem. 23 Q Well, there could be folks at Ethicon who 24 have relevant experience who look at the 25 paper by Anderson and this cobalt solution,</p>	<p>1 trial and tell the Perry jury that based on 2 the testing you did on that single TVT device 3 that there could be degradation in the human 4 body by a certain time point? 5 MR. KUNTZ: Objection. 6 A I've not testified and I don't plan -- I've 7 been saying and I still say that it's 8 unpredictable. There is no certain time 9 point. It's unpredictable. 10 BY MR. SNELL: 11 Q Okay. I just want to make sure I understand 12 how far you were going to try to take this 13 study. 14 Just so we're crystal clear, you're not 15 going to walk into that trial and say, at one 16 year, you can see degradation from the TVT 17 mesh, and I know it because of the study I 18 did on the TVT device? 19 A No, I'm not saying that. 20 Q Okay. Did you do power calculations on your 21 TVT device study? 22 A It's an in vitro test. We typically do power 23 calculations on preclinical studies. But in 24 the in vitro test, it's in vitro, where it's 25 -- you know, it's --</p>
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<p>1 and say that test doesn't actually look like 2 it or is representative of the foreign body 3 reaction in the body. I mean, couldn't 4 scientists come to that conclusion? 5 A They could. But, again, this is a 6 well-accepted test that's been cited a lot 7 and used a lot. I think it should at least 8 raise some questions, especially when you 9 have your own studies showing evidence of 10 oxidation. So it's not only the literature, 11 but it's also these own suture studies, the 12 dog study, Guidon study, that showed evidence 13 of oxidation that should have sent off some 14 red flags, hey, this material is sensitive to 15 oxidation, why don't we test it. That is 16 what I am saying. 17 MR. SNELL: Let's take a break 18 here. We've been going for a while. 19 (A brief recess is taken from 20 4:30 to 4:40 p.m.) 21 BY MR. SNELL: 22 Q Doctor, I want to circle back around to your 23 test, the testing that you were involved in. 24 I just want to make sure that based on 25 that test, you're not going to come into</p>	<p>1 Q You need to do power calculations on the 2 front end of this test if you're going to try 3 to do statistical significant testing on the 4 back end, isn't that correct? 5 A My experience with power calculations, again, 6 is typically in an in vivo study where we 7 estimate -- it's so that we ensure that our 8 study is power enough. If we estimate a 9 certain variance in a certain number is 10 10 percent, we want to be able to power our 11 study to make sure that we can see that 12 10-percent effect. 13 But this is an in vitro study, so, well, 14 we did the study, and either we will see a 15 significant difference or we won't. That's 16 what it is. If we don't see a significant 17 difference, then maybe the study wasn't 18 underpowered, but we report that it is if 19 it's not significant. But it's either 20 significant or it's not. 21 I mean, the reason you do a power study 22 in a preclinical study is to make sure you 23 have got enough animals to do your study. In 24 an in vitro study, well, if we don't see 25 significant differences in the in vitro</p>

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<p>1 study, then our conclusion would be that it's</p> <p>2 just not a significant difference.</p> <p>3 Q Isn't it true, Doctor, that if you do not do</p> <p>4 power calculations on the front end of a</p> <p>5 study, you can't say that there are</p> <p>6 statistically significant findings on the</p> <p>7 back end, because you haven't even assessed</p> <p>8 whether you have an adequately powered study?</p> <p>9 MR. KUNTZ: Objection.</p> <p>10 A I don't think that's true in in vitro</p> <p>11 studies. I don't see people doing this. I</p> <p>12 don't see papers where people power their in</p> <p>13 vitro studies. We typically do enough</p> <p>14 replicates that we can calculate a standard</p> <p>15 deviation and run an ANOVA or a t-test or</p> <p>16 something, but we don't -- in a clinical</p> <p>17 trial and in an animal study, we do power</p> <p>18 analysis all the time, but I just -- I</p> <p>19 don't --</p> <p>20 BY MR. SNELL:</p> <p>21 Q Did you estimate the potential rate of error</p> <p>22 in your study before it was done?</p> <p>23 A Potential rate of error in --</p> <p>24 Q In finding discrepant findings?</p> <p>25 A I just don't know where you are going with</p>	<p>1 can't see differences, you don't know -- it's</p> <p>2 part of justifying the numbers of animals</p> <p>3 that you're going to use in your test. But</p> <p>4 if you have two sets of data, you can compare</p> <p>5 whether they are statistically different or</p> <p>6 not. This is what people do. It's an in</p> <p>7 vitro test. I just don't know where you are</p> <p>8 coming from.</p> <p>9 Q When you do studies, you want to have</p> <p>10 adequate sample sizes so that you can tell if</p> <p>11 the results are meaningful. That's a fair</p> <p>12 statement, right?</p> <p>13 A Yes, but you can tell if the results are</p> <p>14 significantly different if you see a</p> <p>15 significant difference. You can calculate a</p> <p>16 P value. You can do a t-test. You can do an</p> <p>17 ANOVA on that date. If you don't see a</p> <p>18 significant difference, then one reason could</p> <p>19 be you didn't have enough replicates. But if</p> <p>20 you see a significant difference, I don't</p> <p>21 understand how it's not significant. If you</p> <p>22 see a significant difference between two</p> <p>23 groups, they're different. That means the</p> <p>24 differences are -- I don't understand. I</p> <p>25 mean, this is like statistics that you learn</p>
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<p>1 this.</p> <p>2 Q Did you do it or didn't you do it? Did you</p> <p>3 do a calculation to assess the potential rate</p> <p>4 of error before you started that study on the</p> <p>5 TVT device?</p> <p>6 A We didn't do that calculation.</p> <p>7 Q Did you estimate the variance as you noted</p> <p>8 earlier?</p> <p>9 A But this isn't the way statistics works. I</p> <p>10 mean, if we have two populations, we can</p> <p>11 compare by a t-test. We can compare those</p> <p>12 populations and draw within -- we assess P to</p> <p>13 be .05, and so with this value of P, we can</p> <p>14 say it's significant or not significant.</p> <p>15 That's typically what people do in in vitro</p> <p>16 studies. We say P is .05, and then we do</p> <p>17 this -- we can calculate a P value. You can</p> <p>18 do it either way.</p> <p>19 But if you have two populations, you can</p> <p>20 compare those populations using statistical</p> <p>21 analyses. My experience with these power</p> <p>22 analyses is a lot of it comes down to an</p> <p>23 ethics concern. It's not ethical to do an</p> <p>24 animal study that is insufficiently powered.</p> <p>25 Because if you do the study, and you</p>	<p>1 in school. I mean, comparing two</p> <p>2 populations.</p> <p>3 Q Yeah, but here the two populations was a TVT</p> <p>4 device and a polypropylene pellet. It wasn't</p> <p>5 100 TVT devices and 100 pellets, was it?</p> <p>6 A You are so confused on statistics. I made</p> <p>7 this clear. We tested one exemplar, but we</p> <p>8 cut multiple pieces from each exemplar. So</p> <p>9 we have replicates. So we can say,</p> <p>10 statistically, in that mesh that we tested is</p> <p>11 there more oxidation from the FTIR spectra at</p> <p>12 week five compared to week four compared to</p> <p>13 these other weeks.</p> <p>14 We can do that test through even just --</p> <p>15 we could do a two-way ANOVA to compare</p> <p>16 changes in time and changes in the mesh or</p> <p>17 between groups and as a function of time. We</p> <p>18 can do that analysis and that can be --</p> <p>19 that's what people do all the time.</p> <p>20 Q You can't do that analysis as between the</p> <p>21 control, though, because you didn't run all</p> <p>22 of the same tests at the same time, correct?</p> <p>23 A I don't remember the details of that. We ran</p> <p>24 the control went out to four weeks. We ran</p> <p>25 the TVT out to five, and I think we might</p>

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<p>1 have had one that went to six weeks, but we</p> <p>2 just didn't have enough sample to go out that</p> <p>3 far.</p> <p>4 But we can do all of these statistical</p> <p>5 analysis, and I will bring it to trial, and</p> <p>6 you can come at me with whatever you want</p> <p>7 about statistics, but I just don't see where</p> <p>8 you are coming from with this. I mean, we</p> <p>9 can do a statistical test to see whether</p> <p>10 there is differences at least in the function</p> <p>11 of time. That's how we are going to assess</p> <p>12 whether it is induced is the amount of</p> <p>13 oxidation at week five significantly greater</p> <p>14 than what we see at weeks, four, three, two,</p> <p>15 one or zero.</p> <p>16 Q That hasn't been done, though, to this point?</p> <p>17 Or you didn't bring that with you today,</p> <p>18 right?</p> <p>19 A It hasn't been done. We're working on it.</p> <p>20 Q The tensile string, is that anything that you</p> <p>21 tested in this test of the TVT versus the</p> <p>22 control?</p> <p>23 MR. KUNTZ: Objection.</p> <p>24 A We didn't measure tinsel strength. This</p> <p>25 takes a lot of material. And, again, it</p>	<p>1 piece of mesh in Mrs. Perry's body became</p> <p>2 unstable from a polymer standpoint?</p> <p>3 A No, I'm not.</p> <p>4 Q Are you aware of any evidence that the piece</p> <p>5 of mesh in Mrs. Perry became brittle?</p> <p>6 A No, I'm not aware of that.</p> <p>7 Q Are you aware of any evidence that the piece</p> <p>8 of mesh in Mrs. Perry degraded?</p> <p>9 A No.</p> <p>10 Q I didn't ask you at the beginning. Have you</p> <p>11 given testimony at all since the Huskey trial</p> <p>12 as an expert --</p> <p>13 A I provided this listing.</p> <p>14 Q -- against anybody? I think you're right.</p> <p>15 MR. KUNTZ: He gave you an</p> <p>16 updated copy since the Huskey trial. I think</p> <p>17 you have it.</p> <p>18 A I gave testimony in Boston Scientific since</p> <p>19 the Huskey trial.</p> <p>20 MR. SNELL: I have it right</p> <p>21 here. I'm going to mark it.</p> <p>22 (Deposition Exhibit No. 5 was</p> <p>23 marked for identification.)</p> <p>24 BY MR. SNELL:</p> <p>25 Q Doctor, I'm handing you Exhibit 5. Tell me</p>
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<p>1 doesn't answer the question of whether it can</p> <p>2 be oxidized. Tensile strength is a bulk</p> <p>3 test. So because it is a bulk test, it's</p> <p>4 testing the whole material. You may or may</p> <p>5 not see -- the problem with doing a tensile</p> <p>6 strength test is --</p> <p>7 MR. SNELL: Can I move to</p> <p>8 strike? I don't want to keep you here later</p> <p>9 than I have to. It was a yes or no really.</p> <p>10 BY MR. SNELL:</p> <p>11 Q Do you do tensile strength?</p> <p>12 A No.</p> <p>13 Q All right. Did you do any elongation testing</p> <p>14 in your --</p> <p>15 A No.</p> <p>16 Q I don't see it in your opinion, but I just</p> <p>17 want to confirm this. You're not going to be</p> <p>18 giving any testimony on what a suitable</p> <p>19 alternative device for the treatment of</p> <p>20 stress urinary incontinence was that was</p> <p>21 equally safe and effective as TVT Abbrevio; is</p> <p>22 that correct?</p> <p>23 A I did not testify on that and I don't plan</p> <p>24 to.</p> <p>25 Q Okay. Are you aware of any evidence that the</p>	<p>1 what that is, please.</p> <p>2 A This is a listing of cases in which I</p> <p>3 provided testimony in the last four years.</p> <p>4 And there are five cases listed here in 2013</p> <p>5 and 2014.</p> <p>6 MR. SNELL: I'd like to mark</p> <p>7 what I believe is your CV as the next</p> <p>8 exhibit.</p> <p>9 (Deposition Exhibit No. 6 was</p> <p>10 marked for identification.)</p> <p>11 BY MR. SNELL:</p> <p>12 Q Doctor, I'm handing you Exhibit No. 6. If</p> <p>13 you would just identify that for the record.</p> <p>14 A This is my CV. It lists all of my academic</p> <p>15 and professional experience.</p> <p>16 Q That's current?</p> <p>17 A Yes.</p> <p>18 Q Okay. Earlier you talked about environmental</p> <p>19 stress cracking?</p> <p>20 A Yes.</p> <p>21 Q Is that something you need to look at on SEM</p> <p>22 to assess?</p> <p>23 A I would assess environmental stress cracking</p> <p>24 by SEM. There are other methods as well, but</p> <p>25 SEM is one.</p>

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<p>1 Q What are the other methods?</p> <p>2 A The microscopy methods with Dr. Iakovlev.</p> <p>3 Q Are you aware of any evidence that the piece</p> <p>4 of mesh in Mrs. Perry has or had</p> <p>5 environmental stress cracking?</p> <p>6 A I'm not aware of any evidence.</p> <p>7 Q Earlier we talked about the concept of</p> <p>8 macrophages in foreign giant body cells being</p> <p>9 quiescent?</p> <p>10 A Yes.</p> <p>11 Q You are aware that those cells can be</p> <p>12 quiescent, correct?</p> <p>13 A I'm aware that this is an active area of</p> <p>14 investigation. I'm aware that there is a lot</p> <p>15 of research activity trying to make these</p> <p>16 cells quiescent or inactivate them. I'm not</p> <p>17 aware of any reports that have definitely</p> <p>18 proven they're quiescent or what makes them</p> <p>19 quiescent. I would be happy to look at it.</p> <p>20 I'm familiar with this idea, but I'm not</p> <p>21 familiar with any studies that have proven</p> <p>22 that or shown under what conditions that can</p> <p>23 occur.</p> <p>24 Q You are aware actually that scientists are</p> <p>25 able to now incubate and generate quiescent</p>	<p>1 A We can buy those from companies. There is an</p> <p>2 immortalized cell line that you can buy.</p> <p>3 Q So my question to you, then, is, do you know</p> <p>4 whether there are available for purchase or</p> <p>5 use quiescent macrophage cells?</p> <p>6 A I don't know. I've never purchased them, but</p> <p>7 that doesn't mean that they happen in the</p> <p>8 human body. Again, without seeing a</p> <p>9 document, it's difficult to comment on that.</p> <p>10 Q How would one definitively prove that</p> <p>11 macrophages in giant cells become quiescent</p> <p>12 in the body?</p> <p>13 A Well, I would challenge it with a foreign</p> <p>14 body, and different time points, harvest the</p> <p>15 cells, and stain for myeloperoxidase. But</p> <p>16 it's -- to assess that they are actually</p> <p>17 quiescent -- I mean, you have to count the</p> <p>18 number of cells, and then look at the amount</p> <p>19 of myeloperoxidase, look for degradation. It</p> <p>20 would be difficult to show that they are</p> <p>21 completely quiescent.</p> <p>22 Q So what would you have to do to prove that</p> <p>23 those cells are activated every day of the</p> <p>24 year for ten years? You would have to do the</p> <p>25 same test, wouldn't you?</p>
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<p>1 tissue macrophages for use in studies? Don't</p> <p>2 you know that?</p> <p>3 A Well, I would like to see the document you're</p> <p>4 referring to. I just said I haven't seen</p> <p>5 that. I am aware of this idea, but I haven't</p> <p>6 seen that study. I would be happy to look at</p> <p>7 it, but I --</p> <p>8 Q My question is not pertaining to a specific</p> <p>9 study. It's do you know whether scientists</p> <p>10 have generated incubated quiescent tissue</p> <p>11 macrophages for use in studies?</p> <p>12 A I'm not sure what you're referring to. I</p> <p>13 mean, I would have to see a study to -- I'm</p> <p>14 aware of this area of research, but I can't</p> <p>15 comment on it without talking about a</p> <p>16 specific study at least. What am I going to</p> <p>17 say? I don't know where --</p> <p>18 Q Let me ask you this. You know that</p> <p>19 scientists manufacture different cell lines</p> <p>20 for use in studies, correct?</p> <p>21 A There are different permanent cell lines that</p> <p>22 are used in cell culture. I use them in my</p> <p>23 own lab.</p> <p>24 Q So somebody, scientists or companies make</p> <p>25 those, correct?</p>	<p>1 A We talked about this earlier. What I know is</p> <p>2 Dr. Iakovlev, whenever we stain for</p> <p>3 myeloperoxidase, we see it. So does that</p> <p>4 conclusively prove that every cell is always</p> <p>5 -- Dr. Anderson's 2008 review says that these</p> <p>6 cells are activated and adherent, and this</p> <p>7 reaction doesn't stop. That's what he says.</p> <p>8 Q How is that proof? What test has been done</p> <p>9 under the proper methodology that shows that</p> <p>10 those cells are always activated every day</p> <p>11 for a long period of time? Has anybody done</p> <p>12 such a test?</p> <p>13 A Not that I know of. But why would they stop?</p> <p>14 Why would they --</p> <p>15 Q Well, I understand that Dr. Anderson may</p> <p>16 believe that or he wrote something to that</p> <p>17 effect. But has that methodology been tested</p> <p>18 to show that they are always in an activated</p> <p>19 state day after day after day?</p> <p>20 A All I can say is that in my experience with</p> <p>21 this is that they are activated. When I</p> <p>22 talked to Dr. Iakovlev, did you stain for</p> <p>23 myeloperoxidase, his response was, why would</p> <p>24 I stain for myeloperoxidase, it has to be</p> <p>25 there.</p>

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<p>1 Q Dr. Iakovlev assumes it's there. But he has</p> <p>2 not tested for myeloperoxidase on a</p> <p>3 continuous basis, daily or weekly basis in</p> <p>4 samples?</p> <p>5 A I tell you what, I think most people will be</p> <p>6 convinced by it.</p> <p>7 Q Can you answer that question, please? That</p> <p>8 is what Dr. Iakovlev believes, right?</p> <p>9 A Yeah.</p> <p>10 Q But has he tested for myeloperoxidase in the</p> <p>11 same samples longitudinally week after week</p> <p>12 after week after week to see that those are</p> <p>13 activated?</p> <p>14 A Not to my knowledge.</p> <p>15 Q All right. And you haven't done that type of</p> <p>16 testing, correct?</p> <p>17 A No. But in my experience, when I see</p> <p>18 macrophages and stain for myeloperoxidase,</p> <p>19 I've not seen this type of stain. I need to</p> <p>20 qualify my comment. When I see this adherent</p> <p>21 macrophages in the foreign giant body cells</p> <p>22 in my work, they appear to be activated.</p> <p>23 Q All right. You can see macrophages and</p> <p>24 they're not activated. That is well known,</p> <p>25 correct?</p>	<p>1 A You already asked this. I said I don't know</p> <p>2 of a study that showed that. I'm just going</p> <p>3 from my own experience.</p> <p>4 Q Do you know if Dr. Iakovlev has done any type</p> <p>5 of longitudinal study of myeloperoxidase and</p> <p>6 what it should show when properly applied to</p> <p>7 samples from the same source over time?</p> <p>8 A I mean, he's a pathologist. He looks at</p> <p>9 patient explants. You can't do a study like</p> <p>10 that in patients, so I don't believe that he</p> <p>11 has done that study.</p> <p>12 Q Did you bring anything else that we haven't</p> <p>13 marked?</p> <p>14 A I think that's it.</p> <p>15 Q When you do statistical significance testing,</p> <p>16 do you try to generate confident symbols as</p> <p>17 well?</p> <p>18 A Sometimes. It depends on what we're trying</p> <p>19 to do. Sometimes when we establish P at .05,</p> <p>20 sometimes we can calculate a P value. We've</p> <p>21 done several different things.</p> <p>22 Q Have you actually personally ever calculated</p> <p>23 a Bonferroni correction for multiple</p> <p>24 comparison?</p> <p>25 A When I was in graduate school. My students</p>
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<p>1 A I don't know that I would say that that is</p> <p>2 well-known. I don't know under what</p> <p>3 conditions -- I mean, I would have to see a</p> <p>4 study.</p> <p>5 Q Well, let me make it simple. Can macrophages</p> <p>6 be present and they're not activated?</p> <p>7 A In theory, it's possible. I'm just going by</p> <p>8 my own experience. When I see these adherent</p> <p>9 macrophages, they're activated. They're</p> <p>10 secreting this myeloperoxidase. There is</p> <p>11 degradation. That is what I've seen. I will</p> <p>12 be happy to look at an example where that is</p> <p>13 not the case, but --</p> <p>14 Q If there are chronic inflammatory cells</p> <p>15 present, that does not necessarily mean that</p> <p>16 they are active. Is that a fair statement?</p> <p>17 A It's my opinion that they are active. I</p> <p>18 mean, I -- can I say that there is a study</p> <p>19 showing that they are always active all the</p> <p>20 time, no. But I believe they are active</p> <p>21 unless somebody shows they are not, and I</p> <p>22 would like to know under what conditions made</p> <p>23 them not active.</p> <p>24 Q There is no test or study that shows that</p> <p>25 these inflammatory cells are always active?</p>	<p>1 do those calculations now, and I review them.</p> <p>2 There are software programs that you can use</p> <p>3 to do this. It's pretty routine, I think.</p> <p>4 Q The software plugs in the number of tests and</p> <p>5 the time points and it generates --</p> <p>6 A We can do this with software, yeah.</p> <p>7 Q You haven't published or presented on this</p> <p>8 test, correct, that was done with the TVT</p> <p>9 device and the pellet control?</p> <p>10 A We presented it at the AICHE annual meeting.</p> <p>11 And I think those slides are on the reliance</p> <p>12 list.</p> <p>13 Q For the TVT?</p> <p>14 A In that presentation, we did not identify the</p> <p>15 source of the mesh.</p> <p>16 MR. KUNTZ: I don't think that's</p> <p>17 on there, Burt. We will get it to you,</p> <p>18 though.</p> <p>19 A We called it mesh 1, 2 and 3. We did not</p> <p>20 identify it as TVT.</p> <p>21 BY MR. SNELL:</p> <p>22 Q Do you know if it was TVT or would you have</p> <p>23 to go back and look?</p> <p>24 A Yes, it was TVT. We chose not to disclose</p> <p>25 that at that meeting.</p>

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<p>1 Q Where was this at?</p> <p>2 A The AICHE, it's the American Institute of</p> <p>3 Chemical Engineers. If you would like, I can</p> <p>4 circle it on my CV. Would that help you?</p> <p>5 Q Sure. That's fine. Or if you just want to</p> <p>6 look at your CV and tell me what page or</p> <p>7 number.</p> <p>8 A That's fine too. On the CV, it's</p> <p>9 presentation number 154.</p> <p>10 Q Was that a presentation that you actually</p> <p>11 gave and presented or did someone else do it?</p> <p>12 A Dr. Dunn and I both gave the presentation.</p> <p>13 Q Was it presented orally?</p> <p>14 A It was.</p> <p>15 Q Okay. So I would like to request a copy of</p> <p>16 that.</p> <p>17 Did you have to prepare a manuscript in</p> <p>18 connection with that?</p> <p>19 A No. We submitted a short abstract, which is</p> <p>20 available online. We elected not to submit</p> <p>21 an extended abstract.</p> <p>22 Q What was the reason why you didn't submit an</p> <p>23 extended abstract?</p> <p>24 A We typically don't do that for that meeting.</p> <p>25 Q Is that the only presentation you have made</p>	<p>1 to problems such as pain, erosion. The basis</p> <p>2 for this opinion is the Clave, Costello, Wood</p> <p>3 papers where they show changes in the mesh,</p> <p>4 and then how that resulted in degradation.</p> <p>5 And these are all complications, so these are</p> <p>6 meshes that failed.</p> <p>7 And my opinion is that these changes in</p> <p>8 the mesh contributed to those complications</p> <p>9 like pain and erosion. Brittle plastic can</p> <p>10 cause pain. Embrittlement can cause stress</p> <p>11 shielding between the host tissue and the</p> <p>12 implant, which can lead to poor integration,</p> <p>13 erosions, and things like that. These are</p> <p>14 all points that I made previously in Huskey.</p> <p>15 Q In Huskey, though, you didn't testify about</p> <p>16 that at trial as I recall it because you're</p> <p>17 not a medical doctor. Is that consistent</p> <p>18 with your recollection?</p> <p>19 MR. KUNTZ: Objection. Go</p> <p>20 ahead.</p> <p>21 A I think the Judge may have limited what I</p> <p>22 would have liked to have said, but I believe</p> <p>23 it's in the deposition. I don't think</p> <p>24 there is any change in what I'm saying, in</p> <p>25 what I've been saying in these depositions.</p>
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<p>1 concerning the TVT mesh?</p> <p>2 A Yes.</p> <p>3 Q Have you made any other presentations that</p> <p>4 concern transvaginal mesh?</p> <p>5 A That's the only one.</p> <p>6 Q On opinion number one, you say chemical</p> <p>7 degradation, embrittlement, structural</p> <p>8 degradation and other changes.</p> <p>9 A Yes.</p> <p>10 Q Are there any other changes that you're</p> <p>11 referencing that you're going to be talking</p> <p>12 about at trial in the Perry case? That just</p> <p>13 seems kind of broad based, and I want to make</p> <p>14 sure I understand where you're coming from</p> <p>15 with what other changes means.</p> <p>16 A I would probably say I think structural</p> <p>17 degradation, embrittlement, and chemical</p> <p>18 degradation are the primary ones that come to</p> <p>19 mind that I've testified about.</p> <p>20 Q Okay. And number two where it seems to --</p> <p>21 are you going to try to opine that certain</p> <p>22 complications occur in patients like chronic</p> <p>23 inflammation, pain and dyspareunia because of</p> <p>24 the mesh?</p> <p>25 A I'm saying that changes in the mesh can lead</p>	<p>1 Q And just so I'm clear, you didn't conduct any</p> <p>2 type of differential diagnosis to assess the</p> <p>3 cause of dyspareunia or pain or the potential</p> <p>4 causes, correct?</p> <p>5 A No.</p> <p>6 Q You didn't rule out any other cause or</p> <p>7 potential causes?</p> <p>8 A I didn't rule out any other causes.</p> <p>9 Q And you didn't investigate the rates of</p> <p>10 dyspareunia or pain in the general background</p> <p>11 and compare them to these cohorts?</p> <p>12 A I did not.</p> <p>13 Q And in Clave, it's fair to state that one</p> <p>14 cannot say that the complications did not</p> <p>15 occur before the degradation; is that right?</p> <p>16 A It's not clear from Clave the timing of those</p> <p>17 events. My opinion is that these changes in</p> <p>18 the mesh led to those events. The mesh</p> <p>19 changed and there was an adverse event.</p> <p>20 Q And the adverse events are also you mention</p> <p>21 on items number eight and nine, extrusions,</p> <p>22 inflammation, pain, and you mention erosions</p> <p>23 on nine, correct?</p> <p>24 A Yes.</p> <p>25 Q You didn't not do any differential diagnoses</p>

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<p>1 on those, correct?</p> <p>2 A No.</p> <p>3 Q You didn't assess causation by ruling in or</p> <p>4 ruling out different causes, correct?</p> <p>5 A No, I didn't do that.</p> <p>6 Q In the testing that Dr. Kammerer did we</p> <p>7 talked about earlier, where in the first</p> <p>8 5 percent of elongation of the mesh, the</p> <p>9 mechanical-cut and the laser-cut were</p> <p>10 similar, do you dispute that finding?</p> <p>11 A I don't dispute the finding that of the very</p> <p>12 low elongation. They are similar but --</p> <p>13 Q Okay. That's my question.</p> <p>14 A Yeah. Okay.</p> <p>15 Q Did you look at the clinical expert report</p> <p>16 that was done by two medical doctors at</p> <p>17 Ethicon with regard to the laser-cut mesh and</p> <p>18 elongation?</p> <p>19 A I think I reviewed that document, but I can't</p> <p>20 remember what it said right now.</p> <p>21 Q Did that document affect your opinions?</p> <p>22 A I would have to look at it again to see what</p> <p>23 it says. I don't remember.</p> <p>24 Q Did you consider whether either of those</p> <p>25 doctors had any experience implanting slings</p>	<p>1 suggested I talk to Dmochowski, but I</p> <p>2 understand he might have been a defense</p> <p>3 witness, so I haven't done that. I don't</p> <p>4 think I'm supposed to do that. So I have</p> <p>5 reached out to them, but it hasn't moved</p> <p>6 forward.</p> <p>7 Q Has Dr. Dmochowski been an expert in any of</p> <p>8 the other cases you're involved in?</p> <p>9 A I don't know for sure. I don't know if he is</p> <p>10 an expert or not, because I have to resolve</p> <p>11 this before I can contact him. But I have</p> <p>12 reached out to that group at Vanderbilt.</p> <p>13 MR. KUNTZ: I wonder if he has</p> <p>14 disclosed his stuff to Vanderbilt.</p> <p>15 (Deposition Exhibit No. 7 was</p> <p>16 marked for identification.)</p> <p>17 BY MR. SNELL:</p> <p>18 Q I am handing you Exhibit 7 from Vanderbilt.</p> <p>19 Do you recognize this to be from the</p> <p>20 Vanderbilt Health Website?</p> <p>21 A This appears to be urogynecology in the way</p> <p>22 it's printed. I think that's what it is.</p> <p>23 MR. KUNTZ: I'm going to object.</p> <p>24 This is not a complete printout. Are you</p> <p>25 going to show him the part two where they</p>
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<p>1 in women?</p> <p>2 A I would have to look at the document. I just</p> <p>3 don't remember the documents to answer these</p> <p>4 questions. I'd have to look at it.</p> <p>5 Q Have you ever consulted with a</p> <p>6 urogynecologist or a urologist who has</p> <p>7 experience implanting mesh slings to discuss</p> <p>8 with them or learn from them the forces that</p> <p>9 are in play during implantation?</p> <p>10 A No, I have not done that. I relied on the</p> <p>11 Ethicon documents.</p> <p>12 Q The e-mails you were talking about?</p> <p>13 A And the other documents, the reports, the</p> <p>14 papers.</p> <p>15 Q Do you even know Dr. Dmochowski here at</p> <p>16 Vanderbilt?</p> <p>17 A I don't know him.</p> <p>18 Q Do you know that Dr. Dmochowski uses</p> <p>19 polypropylene mesh slings?</p> <p>20 A That's my understanding.</p> <p>21 Q Have you ever written or said anything to any</p> <p>22 of the doctors here at Vanderbilt to apprise</p> <p>23 them of what your opinions are?</p> <p>24 A I have. I have contacted -- there is a</p> <p>25 urogynecologist in the group there, and she e</p>	<p>1 talk about all the mesh complication that</p> <p>2 they treat? Are we going to get the full</p> <p>3 document or just part of it?</p> <p>4 MR. SNELL: You can do whatever</p> <p>5 you want. This is Page 3 of 3.</p> <p>6 MR. KUNTZ: Well, I'm going to</p> <p>7 object to an incomplete document. It's a</p> <p>8 printout of part of the website.</p> <p>9 BY MR. SNELL:</p> <p>10 Q At the top it says, surgical treatments for</p> <p>11 stress urinary incontinence, including mid</p> <p>12 urethral slings. Do you see that?</p> <p>13 A Yes, I'm aware of this. I've seen it.</p> <p>14 Q Well, I guess my question to you is is this a</p> <p>15 website that you visited on the Vanderbilt</p> <p>16 website?</p> <p>17 A I believe I did, because I had to find who to</p> <p>18 contact, but I believe they also do a number</p> <p>19 of revisions.</p> <p>20 MR. SNELL: Move to strike.</p> <p>21 THE WITNESS: Well, you asked.</p> <p>22 I'm sorry.</p> <p>23 BY MR. SNELL:</p> <p>24 Q My question was straight forward.</p> <p>25 A They always are.</p>

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<p>1 Q They really are, sir.</p> <p>2 MR. KUNTZ: Hold on. I'm going</p> <p>3 to object. You are showing him one document,</p> <p>4 and I just made my objection. It is not a</p> <p>5 straight forward question when you're not</p> <p>6 showing him the whole website. And he just</p> <p>7 said where is the website that shows all of</p> <p>8 the complications they're treating for mesh.</p> <p>9 So that is not a straight forward question.</p> <p>10 MR. SNELL: That's not even a</p> <p>11 proper objection. That's not a proper</p> <p>12 objection in California. That's beyond a</p> <p>13 speaking objection.</p> <p>14 MR. KUNTZ: You just said all of</p> <p>15 my questions are straight forward. And this</p> <p>16 is very much a trick question and not a</p> <p>17 straight forward question. So don't make</p> <p>18 your comments unless you --</p> <p>19 MR. SNELL: Let's try it again</p> <p>20 and knock off the ridiculous speaking</p> <p>21 objections.</p> <p>22 MR. KUNTZ: Show him the whole</p> <p>23 website.</p> <p>24 MR. SNELL: Give the man a</p> <p>25 computer. You can have him look at anything.</p>	<p>1 stopped because it's not proper for me to --</p> <p>2 I don't know whether he is a defense witness</p> <p>3 or not, so I would have to resolve this</p> <p>4 before I would really do anything.</p> <p>5 Q You did speak to a female urogynecologist?</p> <p>6 A Yes. I can't remember her name.</p> <p>7 Q Or do you know if she was a urologist?</p> <p>8 A I can't remember. She was in this group.</p> <p>9 She has experience with mesh revisions. And</p> <p>10 one of my students, one of my medical</p> <p>11 students, did a rotation with her, and I</p> <p>12 contacted her, I think, in September, but I</p> <p>13 dropped it because of this concern about</p> <p>14 litigation.</p> <p>15 Q Okay. Do you have any understanding of the</p> <p>16 antioxidants that are in the mesh for the TVT</p> <p>17 Abbrevio?</p> <p>18 A To my knowledge, they are the same as they</p> <p>19 are in proline resin that I talked about at</p> <p>20 trial.</p> <p>21 Q Okay. One of the opinions you gave in Huskey</p> <p>22 was less mesh is better; is that correct?</p> <p>23 A That's correct.</p> <p>24 Q Why don't you give that opinion here?</p> <p>25 A Why don't I give that opinion?</p>
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<p>1 MR. KUNTZ: You bring documents</p> <p>2 and ask him questions. My job is to show up</p> <p>3 with --</p> <p>4 MR. SNELL: You are wasting my</p> <p>5 time. You're giving speaking objections that</p> <p>6 are absolutely improper in California.</p> <p>7 MR. KUNTZ: You are asking trick</p> <p>8 questions, and that's what he told you.</p> <p>9 MR. SNELL: It's not a trick</p> <p>10 question.</p> <p>11 BY MR. SNELL:</p> <p>12 Q Doctor, I read to you surgical treatments for</p> <p>13 stress urinary incontinence include</p> <p>14 mid urethral slings. Did you see that?</p> <p>15 A Yeah, I've seen it.</p> <p>16 Q My question was, have you seen this part of</p> <p>17 the website?</p> <p>18 A I believe so, but it's a printout. It</p> <p>19 doesn't really look the same. I have been on</p> <p>20 that website.</p> <p>21 Q Under what circumstance, would you have gone</p> <p>22 to the website?</p> <p>23 A I was reaching out to that group to discuss</p> <p>24 mesh. I have contacted an OB in that group.</p> <p>25 I can't remember the name right now, but I</p>	<p>1 Q Why aren't you giving that opinion here?</p> <p>2 A I don't think that was specified as an</p> <p>3 opinion. I don't recall that. I thought it</p> <p>4 was in the body of the report. I don't</p> <p>5 remember that being spelled out as a specific</p> <p>6 opinion.</p> <p>7 Q Do you know Abbrevio uses less mesh than</p> <p>8 TVT-O, don't you?</p> <p>9 A What do you mean by uses less mesh? The area</p> <p>10 is smaller, but what about the --</p> <p>11 Q Well, answer my question.</p> <p>12 A I'm trying to clear up the way you're asking</p> <p>13 it. I asking you, do you mean as it has a</p> <p>14 different density or it's a less area?</p> <p>15 That's what I'm asking.</p> <p>16 Q Does TVT Abbrevio have less mesh than the TVT</p> <p>17 obturator?</p> <p>18 A I mean, it has less surface area of mesh, but</p> <p>19 I believe the density of that mesh is still</p> <p>20 the same.</p> <p>21 Q When you say less surface area, you mean it's</p> <p>22 not as long as the TVT-O, correct?</p> <p>23 A Yes, I think that's what I mean.</p> <p>24 Q It's still 1.1 sonometers wide approximately;</p> <p>25 is that correct?</p>

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<p>1 A To my knowledge, and I believe the density is</p> <p>2 the same as well.</p> <p>3 Q When you say density, what do you mean by</p> <p>4 that?</p> <p>5 A Grams per square meter.</p> <p>6 Q Okay. But we can agree there is less mesh</p> <p>7 with TVT Abbrevio than TVT-O?</p> <p>8 A There is less mesh -- the way you say it, I</p> <p>9 guess it's true.</p> <p>10 Q Now, do you have an opinion as to whether TVT</p> <p>11 Abbrevio is the better or a safer device than</p> <p>12 the TVT-O?</p> <p>13 MR. KUNTZ: Objection.</p> <p>14 A No. I'm not comparing it to TVT-O.</p> <p>15 MR. SNELL: I think I'm about</p> <p>16 done. Let me look back through and see if</p> <p>17 there is anything else.</p> <p>18 (A brief recess is taken from</p> <p>19 5:30 to 5:40 p.m.)</p> <p>20 BY MR. SNELL:</p> <p>21 Q Just a few more questions, Doctor. So I'm</p> <p>22 going to request that whatever the materials</p> <p>23 that weren't provided on the testing that was</p> <p>24 done be provided. I'm going to leave the</p> <p>25 deposition open.</p>	<p>1 what we have, and preparing for trial, those</p> <p>2 types of activities.</p> <p>3 Q All right. Is there a list of analyses that</p> <p>4 you can tell me or tell the court reporter</p> <p>5 that you plan to do?</p> <p>6 A Plan to do testing.</p> <p>7 Q With the testing or pertaining to this case?</p> <p>8 A It's the statistical analysis and writing the</p> <p>9 paper. That's it.</p> <p>10 Q What will you do if you do the statistical</p> <p>11 calculations and they turn out to not be</p> <p>12 statistically significant?</p> <p>13 A Report it as not significant, like we always</p> <p>14 do.</p> <p>15 Q What else?</p> <p>16 A What do you mean what else?</p> <p>17 Q What will you do to try to understand why</p> <p>18 they were not statistically significant?</p> <p>19 A I don't know. I would have to think about</p> <p>20 that at the time it -- I don't think that</p> <p>21 that is what is going to happen. The peak is</p> <p>22 ten times bigger, and the aragores (phonetic)</p> <p>23 aren't that -- I believe it's going to be</p> <p>24 significant, and if it's not, then I will</p> <p>25 figure out what to do when that happens. I'm</p>
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<p>1 Is there anything you believe is</p> <p>2 important to your analysis --</p> <p>3 MR. KUNTZ: Hold on. We're not</p> <p>4 leaving the deposition open.</p> <p>5 MR. SNELL: You can say what you</p> <p>6 want to say. I'm leaving it open. I don't</p> <p>7 have all of the documents.</p> <p>8 MR. KUNTZ: California law is</p> <p>9 you can argue --</p> <p>10 MR. SNELL: I'm not going to</p> <p>11 argue with you. I'm either right or wrong.</p> <p>12 MR. KUNTZ: Okay.</p> <p>13 MR. SNELL: I'm either right or</p> <p>14 wrong.</p> <p>15 BY MR. SNELL:</p> <p>16 Q Is there anything you believe is important in</p> <p>17 your opinions and analyses that we have not</p> <p>18 discussed today?</p> <p>19 A I believe we have discussed everything that</p> <p>20 is important.</p> <p>21 Q Now, is there any work that you are planning</p> <p>22 on doing with this case after today?</p> <p>23 A No.</p> <p>24 Q Besides the statistical calculations?</p> <p>25 A No. No testing is planned, just analyzing</p>	<p>1 not going to misrepresent data.</p> <p>2 MR. SNELL: That's fine. I'm</p> <p>3 going to leave the door open. I know counsel</p> <p>4 has a question or two.</p> <p>5 MR. ROSEN: I've got one</p> <p>6 question.</p> <p>7 CROSS-EXAMINATION</p> <p>8 BY MR. ROSEN:</p> <p>9 Q Good evening, Mr. Guelcher. My name is</p> <p>10 Dr. Rosen. I'm with Boyce Schaeffer</p> <p>11 Mainieri. We represent Dr. Luu. I just have</p> <p>12 one question.</p> <p>13 Do you intend to offer any opinions</p> <p>14 regarding Dr. Luu at trial in this matter?</p> <p>15 A I do not. My testimony is about the mesh and</p> <p>16 how it changes after implantation.</p> <p>17 MR. ROSEN: That's all. Thank</p> <p>18 you.</p> <p>19 MR. KUNTZ: Dr. Guelcher, I have</p> <p>20 a few questions for you.</p> <p>21 CROSS-EXAMINATION</p> <p>22 BY MR. KUNTZ:</p> <p>23 Q With respect to the studies you've talked</p> <p>24 about, and the testing you did with Dr. Dunn,</p> <p>25 in the SEM, FTIR, and XPS, those are all</p>

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Scott A. Guelcher, Ph.D.

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<p>1 studies or documents or data that you can</p> <p>2 review independently of Dr. Dunn, correct?</p> <p>3 A Yes, that's correct.</p> <p>4 MR. SNELL: Objection. You've</p> <p>5 got to give me a chance to object. Leading,</p> <p>6 compound. Go ahead.</p> <p>7 BY MR. KUNTZ:</p> <p>8 Q You repeatedly in your practice are going to</p> <p>9 have expertise reviewing those types of</p> <p>10 studies, SEM, FTIR, and XPS?</p> <p>11 MR. SNELL: Objection. Leading</p> <p>12 compound. Go ahead.</p> <p>13 A Yes, I do.</p> <p>14 Q And if Ethicon did those studies or had those</p> <p>15 types of documents, you could review those</p> <p>16 independently, correct?</p> <p>17 MR. SNELL: Same objections.</p> <p>18 A Yes, I could.</p> <p>19 Q The last question I have. Is there any</p> <p>20 peer-reviewed article that you're aware of</p> <p>21 that shows or supports the notion that</p> <p>22 macrophages in foreign body giant cells can</p> <p>23 be deactivated?</p> <p>24 A I'm not aware of such an article.</p> <p>25 MR. KUNTZ: Okay. No more</p>	<p>1 of the response, part of the answer.</p> <p>2 I'm done. Thank you.</p> <p>3 (Deposition was adjourned at 5:50</p> <p>4 p.m.)</p> <p>5 * * *</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
Page 267	Page 269
<p>1 questions.</p> <p>2 REDIRECT EXAMINATION</p> <p>3 BY MR. SNELL:</p> <p>4 Q Are you aware of any book chapters, any</p> <p>5 articles in the peer-reviewed literature that</p> <p>6 says that macrophages can indeed be</p> <p>7 deactivated?</p> <p>8 A I'm not aware of those articles. That's what</p> <p>9 I said earlier.</p> <p>10 Q But you have seen it in the literature or in</p> <p>11 books that macrophages can be quiescent?</p> <p>12 A That's not what I said. I'm familiar with</p> <p>13 this idea of reprogramming macrophages, but I</p> <p>14 am not familiar with any studies that have</p> <p>15 shown that this has been done or under what</p> <p>16 conditions it happens. I mean, I'm familiar</p> <p>17 with the idea. I'm just not familiar with</p> <p>18 such a study is what I'm saying.</p> <p>19 Q You're not familiar with such a study that</p> <p>20 shows that macrophages are activated</p> <p>21 longitudinally every day for years and years?</p> <p>22 A No one has proven that, but Anderson teaches</p> <p>23 they're activated when they adhere. That's</p> <p>24 what it says.</p> <p>25 MR. SNELL: Move to strike part</p>	<p>1 STATE OF KENTUCKY)</p> <p>2)</p> <p>3 COUNTY OF DAVIESS)</p> <p>4</p> <p>5 I, MICHELLE E. KERR, A NOTARY PUBLIC AT LARGE IN</p> <p>6 AND FOR THE COMMONWEALTH OF KENTUCKY, DO HEREBY</p> <p>7 CERTIFY:</p> <p>8 THAT SAID DEPOSITION WAS TAKEN STENOGRAPHICALLY</p> <p>9 AND ELECTRONICALLY BY ME AND THAT THE TYPEWRITTEN</p> <p>10 TRANSCRIPT ABOVE IS A TRUE RECORD OF THE</p> <p>11 TESTIMONY GIVEN; THAT I ALSO RECORDED AND</p> <p>12 TRANSCRIBED ANY AND ALL OBJECTIONS MADE BY COUNSEL</p> <p>13 AND THE REASONS THEREFORE; AND THAT I AM NOT A</p> <p>14 RELATIVE OR EMPLOYEE OR ATTORNEY OR COUNSEL OF ANY</p> <p>15 OF THE PARTIES, NOR A RELATIVE OR EMPLOYEE OF SUCH</p> <p>16 ATTORNEY OR COUNSEL, NOR AM I FINANCIALLY INTERESTED</p> <p>17 IN THIS ACTION.</p> <p>18</p> <p>19</p> <p>20 IN WITNESS WHEREOF, I HAVE HEREUNTO SET MY HAND</p> <p>21 AND AFFIXED MY NOTARIAL SEAL ON THIS ____ DAY OF</p> <p>22 DECEMBER, 2014.</p> <p>23</p> <p>24 MICHELLE E. KERR, NOTARY PUBLIC</p> <p>25 My Commission Expires:</p> <p>March 21, 2017</p> <p>March 21, 2017</p>

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Scott A. Guelcher, Ph.D.

<p style="text-align: right;">Page 270</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition</p> <p>4 over carefully and make any necessary</p> <p>5 corrections. You should state the reason</p> <p>6 in the appropriate space on the errata</p> <p>7 sheet for any corrections that are made.</p> <p>8 After doing so, please sign</p> <p>9 the errata sheet and date it. It will be</p> <p>10 attached to your deposition.</p> <p>11 It is imperative that you</p> <p>12 return the original errata sheet to the</p> <p>13 deposing attorney within thirty (30) days</p> <p>14 of receipt of the deposition transcript</p> <p>15 by you. If you fail to do so, the</p> <p>16 deposition transcript may be deemed to be</p> <p>17 accurate and may be used in court.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 272</p> <p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3 I, _____, do</p> <p>4 hereby certify that I have read the</p> <p>5 foregoing pages, and that the same</p> <p>6 is a correct transcription of the answers</p> <p>7 given by me to the questions therein</p> <p>8 propounded, except for the corrections or</p> <p>9 changes in form or substance, if any,</p> <p>10 noted in the attached Errata Sheet.</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 271</p> <p>1 -----</p> <p>2 E R R A T A</p> <p>3 -----</p> <p>4 PAGE LINE CHANGE</p> <p>5 REASON: _____</p> <p>6 _____</p> <p>7 REASON: _____</p> <p>8 _____</p> <p>9 REASON: _____</p> <p>10 _____</p> <p>11 REASON: _____</p> <p>12 _____</p> <p>13 REASON: _____</p> <p>14 _____</p> <p>15 REASON: _____</p> <p>16 _____</p> <p>17 REASON: _____</p> <p>18 _____</p> <p>19 REASON: _____</p> <p>20 _____</p> <p>21 REASON: _____</p> <p>22 _____</p> <p>23 REASON: _____</p> <p>24 _____</p> <p>25 REASON: _____</p>	<p style="text-align: right;">Page 273</p> <p>1 LAWYER'S NOTES</p> <p>2 PAGE LINE</p> <p>3 _____</p> <p>4 _____</p> <p>5 _____</p> <p>6 _____</p> <p>7 _____</p> <p>8 _____</p> <p>9 _____</p> <p>10 _____</p> <p>11 _____</p> <p>12 _____</p> <p>13 _____</p> <p>14 _____</p> <p>15 _____</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 _____</p> <p>25 _____</p>

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EXHIBIT J

Scott A. Guelcher, Ph.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR))
SYSTEM PRODUCTS LIABILITY) MASTER FILE NO.
LITIGATION) 2:12-MD-02327
) MDL 2327
-----))
THIS DOCUMENT RELATES TO CASE)
CONSOLIDATION:) JOSEPH R. GOODWIN
) U.S. DISTRICT JUDGE
TERRESKI MULLINS, et al.,)
)
Plaintiffs,)
vs.) CASE NO.
) 2:12-CV-02952
ETHICON, INC., et al.,)
)
Defendants.)

DEPOSITION OF

SCOTT A. GUELCHER, Ph.D.

Taken on Behalf of the Defendants

September 15, 2015

Scott A. Guelcher, Ph.D.

Page 2	Page 4
<p>1 APPEARANCES:</p> <p>2 For the Plaintiffs:</p> <p>3 MICHAEL H. BOWMAN, ESQ.</p> <p>4 Wexler Wallace, LLP</p> <p>5 55 West Monroe Street</p> <p>6 Suite 3300</p> <p>7 Chicago, IL 60603</p> <p>8 304.780.8080</p> <p>9 mhb@wexlerwallace.com</p> <p>10 For the Defendants:</p> <p>11 DAVID B. THOMAS, ESQ.</p> <p>12 Thomas Combs & Spann, PLLC</p> <p>13 300 Summers Street</p> <p>14 Suite 1380</p> <p>15 Charleston, WV, 25301</p> <p>16 304.414.1807</p> <p>17 dthomas@tcspllc.com</p> <p>18 CHAD R. HUTCHINSON, ESQ.</p> <p>19 Butler Snow, LLP</p> <p>20 1020 Highland Colony Parkway</p> <p>21 Suite 1400</p> <p>22 Ridgeland, MS 39157</p> <p>23 601.985.4401</p> <p>24 chad.hutchinson@butlersnow.com</p> <p>25</p>	<p>1 Exhibit 10 Degradation Of 36 23</p> <p>2 Polypropylene In Vivo: A</p> <p>3 Microscopic Analysis Of</p> <p>4 Meshes Explanted From</p> <p>5 Patients</p> <p>6 Exhibit 11 Role Of Oxygen In 44 18</p> <p>7 Biodegradation Of</p> <p>8 Poly(etherurethaneura)</p> <p>9 Elastomers</p> <p>10 Exhibit 12 Guelcher PCT-168 Documents 63 1</p> <p>11 Exhibit 13 Materials Characterization 64 7</p> <p>12 And Histological Analysis</p> <p>13 Of Explanted Polypropylene,</p> <p>14 PTFE, and PET Hernia Meshes</p> <p>15 From An Individual Patient</p> <p>16 *** Exhibit 8 was retained ***</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
Page 3	Page 5
<p>1 I N D E X</p> <p>2 WITNESS: SCOTT A. GUELCHER, PH.D.</p> <p>3 INDEX OF EXAMINATIONS</p> <p>4 Page/Line</p> <p>5 By Mr. Thomas 6 5</p> <p>6 By Mr. Bowman 116 2</p> <p>7 I N D E X O F E X H I B I T S</p> <p>8 Page/Line</p> <p>9 Exhibit 1 Expert Report Of Scott 6 14</p> <p>10 Guelcher, Ph.D.</p> <p>11 Exhibit 2 Notice of Deposition of Dr. 6 24</p> <p>12 Scott A. Guelcher</p> <p>13 Exhibit 3 Scott A. Guelcher 7 20</p> <p>14 Curriculum Vitae</p> <p>15 Exhibit 4 Fee Schedule 8 1</p> <p>16 Exhibit 5 Listing Of Cases In Which 10 13</p> <p>17 Testimony Has Been Given In</p> <p>18 the Last Four Years</p> <p>19 Exhibit 6 August 29, 2015, Invoice 11 15</p> <p>20 Exhibit 7 Binder 12 12</p> <p>21 Exhibit 8 Flash Drive 13 20</p> <p>22 Exhibit 9 Abstract Submitted To The 29 20</p> <p>23 IUGA Meeting</p> <p>24</p> <p>25</p>	<p>1 The deposition of SCOTT A. GUELCHER,</p> <p>2 Ph.D., taken on behalf of the Defendants, on</p> <p>3 September 15, 2015, at 9:07 A.M., in the offices</p> <p>4 of Butler Snow, 150 Third Avenue South, Suite</p> <p>5 1600, Nashville, Tennessee, for all purposes under</p> <p>6 the Rules of Civil Procedure.</p> <p>7 The formalities as to notice,</p> <p>8 caption, certificate, et cetera, are waived. All</p> <p>9 objections, except as to the form of the</p> <p>10 questions, are reserved to the hearing.</p> <p>11 It is agreed that Gary Schneider,</p> <p>12 being a Notary Public and Court Reporter for the</p> <p>13 State of Tennessee, may swear the witness, and</p> <p>14 that the reading and signing of the completed</p> <p>15 deposition by the witness are reserved.</p> <p>16</p> <p>17</p> <p>18</p> <p>19 * * *</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

2 (Pages 2 to 5)

Scott A. Guelcher, Ph.D.

Page 6	Page 8
<p>1 SCOTT A. GUELCHER, Ph.D., 2 was called as a witness and, after having been 3 first duly sworn, testified as follows: 4 EXAMINATION 5 BY MR. THOMAS: 6 Q. Good morning, Dr. Guelcher. 7 A. Good morning. 8 Q. We're here today in the deposition -- for 9 your deposition in the Mullins versus Ethicon 10 case, correct? 11 A. Yes. 12 Q. Let me hand you what I'm going to mark as 13 Deposition Exhibit No. 1. 14 (Marked Exhibit 1.) 15 BY MR. THOMAS: 16 Q. And ask you if that's your expert report 17 in this case? 18 A. Yes. 19 Q. And does Deposition Exhibit No. 1 contain 20 the complete set of your opinions that you're 21 prepared to offer in this case that you have at 22 this time? 23 A. Yes. 24 (Marked Exhibit 2.) 25</p>	<p>1 (Marked Exhibit 4.) 2 BY MR. THOMAS: 3 Q. Do you have an hourly rate? 4 A. No. 5 Q. Okay. And how many hours is a half a day? 6 A. I don't know. It's half a day. We decide 7 at the time that the activity was performed. 8 Q. Last time I saw your fees, I think, were 9 in the Perry case. You were charging \$475 an 10 hour; is that right? 11 A. I don't remember. That's in the range. 12 Q. Okay. So Deposition Exhibit No. 4 13 represents your current fees, correct? 14 A. Yes. 15 Q. What happens if you only work for an hour? 16 A. What do you mean only work for an hour? 17 Q. Well, you -- 18 A. With respect to what -- 19 Q. Well -- 20 A. -- activity? 21 Q. -- any -- for labor you charge \$1,250 for 22 a half a day. 23 What happens if you only work for an hour? 24 A. Let me look at the fee sheet again. 25 Q. You have it right there.</p>
Page 7	Page 9
<p>1 BY MR. THOMAS: 2 Q. Let me show you Deposition Exhibit No. 2. 3 Deposition Exhibit No. 2 is your Notice of 4 Deposition in this case. Have you seen that 5 before today? 6 A. Yes. 7 Q. And in response to Deposition Exhibit 8 No. 2, did you seek to collect documents that are 9 responsive to the document requests that are 10 attached to that notice? 11 A. Yes. 12 Q. And what did you bring to me today? 13 A. The notebook is the report with the 14 reliance documents. So the -- I have an updated 15 CV. There's a few papers that have been updated. 16 Q. Okay. 17 A. That's an updated CV. 18 Q. I'm going to mark your updated CV as 19 Deposition Exhibit No. 3. 20 (Marked Exhibit 3.) 21 THE WITNESS: I brought the fee 22 sheet. It's the same as the one in the report. 23 No change there. 24 MR. THOMAS: Okay. I will mark your 25 fee sheet as Deposition Exhibit No. 4.</p>	<p>1 A. So you're looking at -- you're looking at 2 the -- I'm not sure where you're looking, 3 actually. Was it research and analysis? 4 Q. Under labor -- 5 A. Yeah. 6 Q. -- research and analysis, you show half 7 day, full day, \$1,250 for a half a day. Are 8 there -- 9 A. Right. 10 Q. -- days when you only work an hour? 11 A. I don't typically -- so the way I -- I do 12 the billing is I -- I charge a flat rate for a 13 report. And I charge the half day or the full day 14 for travel and testimony. That's the way the 15 billing is done. 16 Q. Okay. So are you doing research and 17 analysis for which you bill your time? 18 A. I don't remember billing time for research 19 and analysis. It's all been -- that I can 20 remember, it's -- I bill for a report or I bill 21 for the testimony or the travel. That's how my 22 billing has been done. 23 Q. Okay. 24 A. It's on the fee sheet, but I don't think 25 I've been using that. I've been billing by</p>

3 (Pages 6 to 9)

Scott A. Guelcher, Ph.D.

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<p>1 reports.</p> <p>2 Q. Okay. And the last entry shows</p> <p>3 deposition, trial preparation. Is that a flat</p> <p>4 rate that you charge to get ready for trial?</p> <p>5 A. That's correct.</p> <p>6 Q. And then if you're testifying at trial, I</p> <p>7 see you have an entry here for \$2,000 for a half a</p> <p>8 day and \$4,000 for a full day; is that correct?</p> <p>9 A. That's correct.</p> <p>10 Q. Okay. What else did you bring?</p> <p>11 A. I brought an updated list of previous</p> <p>12 testimony.</p> <p>13 (Marked Exhibit 5.)</p> <p>14 BY MR. THOMAS:</p> <p>15 Q. I've marked your updated list of previous</p> <p>16 testimony as Deposition Exhibit No. 5.</p> <p>17 Do you have any depositions currently</p> <p>18 scheduled now -- between now and December?</p> <p>19 A. Not that I'm aware. I don't think so.</p> <p>20 Q. Do you have any trials at which you're</p> <p>21 supposed to appear between now and December?</p> <p>22 A. Possibly a Boston Scientific trial in</p> <p>23 October in North Carolina.</p> <p>24 Q. Okay. Do you know the name of that case?</p> <p>25 A. I can't remember. It's a Boston</p>	<p>1 A. That's it. Well, other than this</p> <p>2 notebook, which is the report with many of the</p> <p>3 footnotes.</p> <p>4 Q. Okay.</p> <p>5 A. Do you want to enter that in?</p> <p>6 Q. I always do. You know that. I'm going to</p> <p>7 mark your notebook.</p> <p>8 A. I just would like to have it back so I can</p> <p>9 use it.</p> <p>10 Q. Absolutely will. I'm going to mark your</p> <p>11 notebook as Deposition Exhibit No. 7.</p> <p>12 (Marked Exhibit 7.)</p> <p>13 BY MR. THOMAS:</p> <p>14 Q. And is it fair to describe this as your</p> <p>15 report with all the references that you cite that</p> <p>16 you need -- want to have to talk about?</p> <p>17 A. Not all of the references, but most of the</p> <p>18 references are there.</p> <p>19 Q. Okay.</p> <p>20 MR. THOMAS: And, Counsel, I believe</p> <p>21 you told me before that you have something you</p> <p>22 need to give me?</p> <p>23 MR. BOWMAN: Yes, sir. It's a thumb</p> <p>24 drive.</p> <p>25 MR. THOMAS: Can you tell me what's</p>
Page 11	Page 13
<p>1 Scientific. It was part of the wave. So it</p> <p>2 was -- it was -- I believe it was part of the</p> <p>3 Barba wave.</p> <p>4 Q. Are you --</p> <p>5 A. But I don't remember the case.</p> <p>6 Q. Are you planning to attend that trial as</p> <p>7 you sit here today?</p> <p>8 A. That's my intent.</p> <p>9 Q. Okay.</p> <p>10 A. I think it's the week of the 5th.</p> <p>11 Q. Okay. What else do you have with you</p> <p>12 today?</p> <p>13 A. I have the invoice for the report that I</p> <p>14 prepared for this case.</p> <p>15 (Marked Exhibit 6.)</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. I'll mark the invoice for the report that</p> <p>18 you prepared in this case as Exhibit No. 6.</p> <p>19 Is that the total amount of time that</p> <p>20 you've billed plaintiff's counsel for this matter</p> <p>21 to date?</p> <p>22 A. For this -- for this matter, this is what</p> <p>23 I've billed plaintiff's counsel.</p> <p>24 Q. Okay. What else did you bring with you</p> <p>25 today?</p>	<p>1 on the thumb drive?</p> <p>2 MR. BOWMAN: Yes. That is literature</p> <p>3 and documents that are on his reliance list that</p> <p>4 was already turned over with his report. I also</p> <p>5 have a separate file for testing that was</p> <p>6 requested in the Notice of Deposition. It's</p> <p>7 actually very huge, so I'm going to have to send</p> <p>8 it to you as a link if that's all right.</p> <p>9 MR. THOMAS: So there's additional</p> <p>10 information; is that right?</p> <p>11 MR. BOWMAN: That's right.</p> <p>12 MR. THOMAS: Is that the testing that</p> <p>13 he did on the -- intentionally oxidizing</p> <p>14 polypropylene?</p> <p>15 MR. BOWMAN: So I'm going to let him</p> <p>16 talk about that, but it's in response to the</p> <p>17 deposition request 15.</p> <p>18 MR. THOMAS: Okay. I'm going to mark</p> <p>19 the thumb drive as Exhibit No. 8.</p> <p>20 (Marked Exhibit 8.)</p> <p>21 MR. BOWMAN: For clarity's sake, the</p> <p>22 thumb drive does not contain the testing. The</p> <p>23 testing will be on the link that I send. Is that</p> <p>24 all right?</p> <p>25 MR. THOMAS: That's fine. Is there</p>

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<p style="text-align: right;">Page 14</p> <p>1 anything else that you can tell me that is not on</p> <p>2 the thumb drive, other than the testing that was</p> <p>3 the subject of the request?</p> <p>4 MR. BOWMAN: I can. There were</p> <p>5 objections made to producing all of his testimony</p> <p>6 and reports from all pelvic mesh litigations. And</p> <p>7 there was -- there were objections made to</p> <p>8 producing all of his time as was reported in other</p> <p>9 pelvic mesh litigations. I believe there were</p> <p>10 also objections to things beyond the scope of the</p> <p>11 litigation and as being not responsive per Federal</p> <p>12 Rule 26.</p> <p>13 MR. THOMAS: Okay.</p> <p>14 MR. BOWMAN: And we can get into</p> <p>15 those if you want. But as far as I know,</p> <p>16 everything else is being produced.</p> <p>17 MR. THOMAS: Well, as we discussed, I</p> <p>18 believe you said the objections were filed last</p> <p>19 night. I don't have -- we don't have here today,</p> <p>20 and I don't want to spend time fussing about that</p> <p>21 because we've -- I'd like to get out of here</p> <p>22 early, and I'm sure you would too.</p> <p>23 MR. BOWMAN: Frankly, I couldn't</p> <p>24 argue with you if I wanted to, so...</p> <p>25 MR. THOMAS: Well, there we have it.</p>	<p style="text-align: right;">Page 16</p> <p>1 deposition in the Perry case.</p> <p>2 A. Yes.</p> <p>3 Q. Have you reviewed your testimony in the</p> <p>4 Huskey case and the Perry case in preparation for</p> <p>5 this deposition?</p> <p>6 A. Yes, I've reviewed some of that testimony.</p> <p>7 Q. Is there anything about your answers in</p> <p>8 either the Huskey case or the Perry case that you</p> <p>9 believe are -- to be incomplete or inaccurate?</p> <p>10 A. No. I believe my opinions have largely</p> <p>11 stayed the same, and there's new information that</p> <p>12 further supports the opinions, but they haven't</p> <p>13 changed in the basic essence.</p> <p>14 Q. And the reason why I asked the question,</p> <p>15 just to be fair and clear, is that you've already</p> <p>16 been deposed at length on some very --</p> <p>17 A. I understand.</p> <p>18 Q. -- basic stuff in your reports, and I just</p> <p>19 don't want to go over it again.</p> <p>20 A. I understand.</p> <p>21 Q. Is there any reason for me to ask you</p> <p>22 about your prior testimony, either the Huskey case</p> <p>23 or the Perry case, for you -- to give you a chance</p> <p>24 to further explain your opinions?</p> <p>25 A. I don't believe so.</p>
<p style="text-align: right;">Page 15</p> <p>1 MR. BOWMAN: Yes. All right.</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. Doctor, you heard counsel's explanation of</p> <p>4 the information that's contained on the thumb</p> <p>5 drive. Did you prepare the thumb drive?</p> <p>6 A. I did not.</p> <p>7 Q. Okay. You heard him describe some testing</p> <p>8 that's not on the thumb drive that's going to be</p> <p>9 supplied to us by a link. What is that?</p> <p>10 A. That was the testing that Dr. Dunn did on</p> <p>11 several meshes. And it was produced at Perry</p> <p>12 deposition.</p> <p>13 Q. Is there anything new and different</p> <p>14 produced in that testing that I'm going to get by</p> <p>15 link today that hasn't been produced in the Perry</p> <p>16 case?</p> <p>17 A. Not to my knowledge. I don't -- I believe</p> <p>18 it's the same information.</p> <p>19 Q. Did you review that information before it</p> <p>20 had been supplied to counsel to give to me?</p> <p>21 A. I did not. I -- it came directly from</p> <p>22 Dr. Dunn.</p> <p>23 Q. Okay. Dr. Guelcher, you know I've had the</p> <p>24 opportunity to take your deposition on a couple of</p> <p>25 times, and I believe Burt Snell took your</p>	<p style="text-align: right;">Page 17</p> <p>1 Q. Okay. Since your deposition in the Huskey</p> <p>2 case, have you had any further training in polymer</p> <p>3 science?</p> <p>4 A. What do you mean by training?</p> <p>5 Q. Anything that adds to your skill set to</p> <p>6 you to evaluate these meshes.</p> <p>7 MR. BOWMAN: Object.</p> <p>8 THE WITNESS: It's been a year. I</p> <p>9 have -- I've published several new papers. Do you</p> <p>10 want me to -- I'm not sure what you're asking me.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Well --</p> <p>13 A. Do you want me to go through new papers,</p> <p>14 new presentations? I'm not...</p> <p>15 Q. Papers and presentations, I don't need to</p> <p>16 you go through them in detail, but is that what</p> <p>17 you're referring to as being the additional work</p> <p>18 that you've done since we were last together?</p> <p>19 A. Well, I'm hung up on the word "training."</p> <p>20 Training to me means taking a class. I have</p> <p>21 additional experience.</p> <p>22 Q. Okay. Have you had any additional</p> <p>23 classes?</p> <p>24 A. Classes on?</p> <p>25 Q. Polymer science.</p>

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<p>1 A. I mean, I teach classes. I don't</p> <p>2 generally take them, so...</p> <p>3 Q. I understand. But the answer to the</p> <p>4 question is no, correct?</p> <p>5 A. No.</p> <p>6 Q. Okay. But you have done additional</p> <p>7 research?</p> <p>8 A. Yes.</p> <p>9 Q. And you have presented papers?</p> <p>10 A. Yes.</p> <p>11 Q. Is that the extent of the additional work</p> <p>12 that you've done since we were together last in</p> <p>13 Huskey?</p> <p>14 A. It's all research related.</p> <p>15 Q. Okay. And research related to this</p> <p>16 litigation?</p> <p>17 A. How does research relate to the</p> <p>18 litigation? You mean -- I'm not sure what you</p> <p>19 mean.</p> <p>20 Q. Well, what I'm trying to understand is the</p> <p>21 additional work or knowledge that you've gained --</p> <p>22 A. Right.</p> <p>23 Q. -- since the Huskey deposition, is that</p> <p>24 information and knowledge that you've gained</p> <p>25 through your research in this litigation?</p>	<p>1 Dr. Iakovlev. I'm sorry. Could you repeat the --</p> <p>2 you're -- you're referring back to Huskey trial?</p> <p>3 Q. The Huskey deposition.</p> <p>4 A. Huskey deposition.</p> <p>5 Q. That's right.</p> <p>6 A. Okay. So the new work that's been done is</p> <p>7 the study with Dr. Dunn that was funded by his</p> <p>8 company. Mr. Snell deposed me on this in the</p> <p>9 Perry case. It was produced in Perry by Jeff</p> <p>10 Kuntz. So Mr. Snell deposed me on it. But it was</p> <p>11 part of research at Vanderbilt, paid for by</p> <p>12 Dr. Dunn's company. Then there's the paper with</p> <p>13 Dr. Iakovlev, and then there's the IUGA meeting</p> <p>14 that I went to in June.</p> <p>15 Q. And where was the IUGA meeting?</p> <p>16 A. It was in France.</p> <p>17 Q. And who paid for you to attend the IUGA</p> <p>18 meeting in France?</p> <p>19 A. I paid. It was not part of the</p> <p>20 litigation.</p> <p>21 Q. Did you attend -- did any plaintiff's</p> <p>22 counsel attend that meeting?</p> <p>23 A. For any mesh litigation?</p> <p>24 Q. Yes.</p> <p>25 A. Okay. There either were two attorneys...</p>
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<p>1 A. Well, it's -- it's in my updated CV. My</p> <p>2 report has some discussion of new references. So</p> <p>3 I would say that there's new papers and new</p> <p>4 presentations that are either on the CV or</p> <p>5 discussed in the report that reflect my updated</p> <p>6 knowledge and understanding of pelvic mesh over</p> <p>7 the past year.</p> <p>8 Q. And the updated knowledge and</p> <p>9 understanding that you have about pelvic mesh over</p> <p>10 the last year has been gained through your work in</p> <p>11 this litigation, fair?</p> <p>12 A. Not exclusively. Not -- not the</p> <p>13 litigation. When I think in terms of litigation,</p> <p>14 I'm thinking in terms of what's been billed to the</p> <p>15 litigation. And what's been billed to the</p> <p>16 litigation is reports, depositions, trial</p> <p>17 testimony. That's what's been billed to</p> <p>18 litigation. The other work is through my</p> <p>19 professional appointment at Vanderbilt where I do</p> <p>20 research. So -- so that's all Vanderbilt</p> <p>21 research.</p> <p>22 Q. What Vanderbilt research have you done</p> <p>23 since we were together last on the -- on pelvic</p> <p>24 mesh issues?</p> <p>25 A. Well, I co-authored a paper with</p>	<p>1 Q. And who attended that meeting that you</p> <p>2 knew --</p> <p>3 A. Margaret Thompson and Bri Olson (phonetic)</p> <p>4 from Motley Rice.</p> <p>5 Q. And did you work with Ms. Thompson or</p> <p>6 Ms. Olson while you were in France on the issues</p> <p>7 presented by this litigation?</p> <p>8 A. So Ms. Thompson requested a workshop, a</p> <p>9 mock trial workshop at the IUGA meeting. And I</p> <p>10 participated in that mock trial workshop.</p> <p>11 Q. And what did you do at the mock trial</p> <p>12 workshop at the IUGA meeting?</p> <p>13 A. I was an expert witness.</p> <p>14 Q. Were you compensated for your time?</p> <p>15 A. No.</p> <p>16 Q. Who else participated in the mock trial</p> <p>17 workshop?</p> <p>18 A. Dr. Iakovlev, Dr. Carey, Dr. Ostergard.</p> <p>19 That's all I remember.</p> <p>20 Q. And was this mock trial workshop put</p> <p>21 together by Dr. Thompson?</p> <p>22 A. It was.</p> <p>23 Q. And what did you do to prepare for that</p> <p>24 mock trial workshop?</p> <p>25 A. Well, Ms. Thompson prepared slides for my</p>

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<p>1 direct exam. And she prepared handouts for the</p> <p>2 attendees who -- the people who attended the</p> <p>3 workshop were divided into two juries, and</p> <p>4 Ms. Thompson gave them several documents.</p> <p>5 Q. And who conducted your direct examination?</p> <p>6 A. Ms. Thompson.</p> <p>7 Q. Were there any other lawyers other than</p> <p>8 Margaret Thompson and Bri Olson who were present</p> <p>9 at the IUGA meeting that you met with?</p> <p>10 A. I don't know everyone who was in the</p> <p>11 audience. I don't know.</p> <p>12 Q. And the people who attended the workshop</p> <p>13 were doctors?</p> <p>14 A. There was a mix. They were doctors,</p> <p>15 Ph.D.s, maybe some trainees. There was a mix of</p> <p>16 people. I didn't meet all of them.</p> <p>17 Q. Do you have a list of attendees?</p> <p>18 A. I don't. The IUGA would have that, the</p> <p>19 people who registered for the workshop. Margaret</p> <p>20 Thompson may have that. I don't have it that I</p> <p>21 know. I don't believe I have that.</p> <p>22 Q. Do you still have a set of the slides that</p> <p>23 you used at the mock trial?</p> <p>24 A. I was told by plaintiff's counsel that</p> <p>25 there are objections pending on that.</p>	<p>1 Q. That's right.</p> <p>2 A. So I -- I paid for it out of my faculty</p> <p>3 development fund at Vanderbilt as a discretionary</p> <p>4 expense.</p> <p>5 Q. Did you receive any compensation from</p> <p>6 plaintiff's counsel for your participation in the</p> <p>7 workshop?</p> <p>8 A. No.</p> <p>9 Q. You know that all the people you've</p> <p>10 identified have testified as witnesses for the</p> <p>11 plaintiffs in the mesh litigation?</p> <p>12 A. I do.</p> <p>13 Q. Do you know whether there was any effort</p> <p>14 to present expert witnesses from the defense</p> <p>15 litigation?</p> <p>16 A. Ms. Thompson could speak to that. I can</p> <p>17 say that there were no defense witnesses. I -- I</p> <p>18 don't know if there was an attempt or not. She</p> <p>19 would know. But there was a cross-exam, but there</p> <p>20 were no defense witnesses, and I don't know why.</p> <p>21 Q. Did -- who conducted the cross-exam?</p> <p>22 A. Ms. Olson.</p> <p>23 Q. Was the presentation videotaped?</p> <p>24 A. I don't know.</p> <p>25 Q. Do you know whether the presentation was</p>
Page 23	Page 25
<p>1 Q. Okay. But do you still have a set of</p> <p>2 those slides?</p> <p>3 A. I believe so. But I haven't looked at --</p> <p>4 I'm not really sure.</p> <p>5 Q. Okay. And have you -- those are slides</p> <p>6 that you did not produce to me today?</p> <p>7 A. I did not produce them at all. They're</p> <p>8 someone else's property. I mean, Ms. Thompson</p> <p>9 prepared the slides for me.</p> <p>10 Q. Okay. Have you seen the other slides</p> <p>11 produced by the other witnesses, Dr. Iakovlev,</p> <p>12 Dr. Carey, and Dr. Ostergard?</p> <p>13 A. I don't believe so.</p> <p>14 Q. Okay.</p> <p>15 A. I don't think I saw that. I saw them</p> <p>16 present their slides, but I don't have their</p> <p>17 slides. I have my slides.</p> <p>18 Q. Did you take any notes?</p> <p>19 A. No.</p> <p>20 Q. Did anyone subsidize your expenses for</p> <p>21 your trip to France for the IUGA meeting?</p> <p>22 A. So what do you mean by subsidize my</p> <p>23 expenses?</p> <p>24 Q. Did anybody help you pay for it?</p> <p>25 A. Reimburse?</p>	<p>1 recorded by stenography?</p> <p>2 A. I don't know that either.</p> <p>3 Q. Is this IUGA meeting the same place where</p> <p>4 you made a presentation to the group on --</p> <p>5 A. Are you referring to the PP29, the in</p> <p>6 vitro oxidation study? Yes.</p> <p>7 Q. That's right.</p> <p>8 A. It was that -- the workshop was on</p> <p>9 Wednesday, and I think the talk was later. I'm</p> <p>10 not -- I don't remember the date. It was after.</p> <p>11 Q. How long was the meeting?</p> <p>12 A. Four days. I don't know.</p> <p>13 Q. How long were you in France?</p> <p>14 A. Ten or eleven days.</p> <p>15 Q. And other than -- did you attend the</p> <p>16 meeting all four days?</p> <p>17 A. Not all day, but I went to the meeting</p> <p>18 several days. I don't remember exactly which</p> <p>19 days.</p> <p>20 Q. What else did you do during your time in</p> <p>21 France?</p> <p>22 A. So my wife came with me. I paid for her</p> <p>23 to come, and she came with me.</p> <p>24 Q. Good.</p> <p>25 Other than your work with Margaret</p>

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<p>1 Thompson and Bri Olson and the workshop, did you 2 have any other work on the pelvic mesh litigation 3 while you were on your trip? 4 A. What do you mean work? On the litigation 5 or on -- 6 Q. Correct. On the pelvic mesh. Anything -- 7 anything -- I'm sorry. 8 A. I'm sorry. Go ahead, yeah. I -- 9 Q. I just want to -- 10 A. Yeah. 11 Q. -- define my question. 12 A. Yeah, that's what... 13 Q. You obviously spent almost a week more -- 14 A. Mm-hmm. 15 Q. -- in France while you were there. 16 A. Mm-hmm. 17 Q. And you either spent it vacationing with 18 your wife, which I hope you did, or you spent at 19 least part of it doing some other work with 20 plaintiff's counsel or meeting with other -- 21 A. I understand. 22 Q. -- people over there to talk about the 23 issues about which you're testifying today. 24 A. Okay. Now I understand. So I'll try to 25 be a little more specific. We were there two</p>	<p>1 confidential. I mean, I haven't -- these grants 2 are all confidential when they're submitted, so I 3 don't think it's appropriate to -- to discuss my 4 ideas. It's not part of my testimony. It's not 5 in my report. It's not -- I'm not talking about 6 my externally funded research in this report. I'm 7 talking about, you know, the opinions that are in 8 here. So that's not part of my report. 9 Q. Do the -- strike that. 10 Are the ideas that you discussed with 11 Dr. Carey designed to answer questions that are 12 posed in this litigation? 13 MR. BOWMAN: Object to form. 14 THE WITNESS: That's very -- what do 15 you mean questions posed by this litigation? 16 Could you be more -- I'm not -- I'm not sure what 17 you're asking me. 18 BY MR. THOMAS: 19 Q. I'm just trying -- there are various 20 medical and scientific issues that are debated by 21 Ethicon and the plaintiffs in this litigation, and 22 you're involved in some of those issues. 23 My question is whether the research that 24 you discussed with Dr. Carey is designed to 25 further your knowledge and understanding about the</p>
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<p>1 weekends, so on the weekends we were doing other 2 things. During the meeting, we -- we met for the 3 workshop, and then everybody went their separate 4 ways. So there was -- I think I had some 5 conversations with Dr. Iakovlev about our 6 manuscript that was being reviewed. I talked with 7 Dr. Carey about writing a research grant to the 8 NIH on mesh. I -- there wasn't -- I don't 9 remember any discussion of the litigation. It 10 was -- it was research. What I would call 11 research, which I would call within the context of 12 my position at Vanderbilt, which is writing 13 research proposals, writing papers, and mentoring 14 students. 15 Q. What's the topic of the research grant to 16 NIH that you discussed with Dr. Carey? 17 A. Well, I haven't submitted it yet, so it's 18 all, you know, confidential, new ideas. I don't 19 have any -- I haven't written anything yet. 20 Q. Do you -- are you -- not that I'm going to 21 argue about it. 22 A. Yeah. 23 Q. Are you refusing to share your ideas with 24 me? 25 A. I don't want to. It's -- it's still</p>	<p>1 issues about which you're testifying today. 2 A. I would say it's more forward looking. 3 It's about finding new solutions, not so much 4 about -- it's separate from this. 5 Q. Does it concern an alternative to mesh? 6 A. It could. 7 Q. You're not -- you're not going to tell me? 8 A. No. 9 Q. Okay. 10 A. I don't -- 11 Q. I'm not going to argue with you anymore. 12 A. I mean, this is research that's protected. 13 Q. Protected by what? 14 A. By confidentiality. When I submit a grant 15 to the NIH, the reviewers who review those 16 documents all have to keep it confidential. And 17 it hasn't even been submitted yet. So it needs to 18 be confidential. 19 Q. Okay. 20 (Marked Exhibit 9.) 21 BY MR. THOMAS: 22 Q. You mentioned a minute ago PP29. Let me 23 hand you what I've marked as Deposition Exhibit 24 No. 9 and ask you if that's the reference that you 25 just discussed.</p>

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<p>1 A. It is.</p> <p>2 Q. Tell me what Exhibit No. 9 is.</p> <p>3 A. So this is an abstract that was submitted</p> <p>4 to the IUGA meeting. It was accepted for an oral</p> <p>5 presentation, and it was published in the</p> <p>6 supplement in the International Urogynecology</p> <p>7 Journal this year.</p> <p>8 Q. And did you write Exhibit No. 9?</p> <p>9 A. I co-authored it with Dr. Dunn.</p> <p>10 Q. Who was the primary author?</p> <p>11 A. Well, I was.</p> <p>12 Q. All right. And what contribution did</p> <p>13 Dr. Dunn make to the writing of Exhibit No. 9?</p> <p>14 A. I don't remember.</p> <p>15 Q. Okay.</p> <p>16 A. I don't remember.</p> <p>17 Q. And Exhibit No. 9 is a discussion of the</p> <p>18 research that you and Dr. Dunn conducted that was</p> <p>19 produced and discussed in the Perry litigation,</p> <p>20 fair?</p> <p>21 A. Yeah, it was produced and it was</p> <p>22 discussed. But Dr. Dunn was not deposed on it.</p> <p>23 It wasn't -- it was withdrawn from the Perry</p> <p>24 litigation.</p> <p>25 Q. Okay. And I believe you said that you</p>	<p>1 THE WITNESS: The message? You mean</p> <p>2 the conclusions?</p> <p>3 BY MR. THOMAS:</p> <p>4 Q. Right. What were you trying to convey to</p> <p>5 your audience?</p> <p>6 A. That oxidative -- it's stated in the</p> <p>7 conclusions. Oxidative degradation of</p> <p>8 polypropylene pelvic mesh was evidenced by</p> <p>9 chemical and physical changes under simulated in</p> <p>10 vivo conditions. That was the conclusion from the</p> <p>11 study.</p> <p>12 Q. Okay. And did you discuss the actual</p> <p>13 experiment that you and Dr. Dunn conducted with</p> <p>14 the group?</p> <p>15 A. I did. It's in the slides.</p> <p>16 Q. All right.</p> <p>17 A. I had a slide showing the methods.</p> <p>18 Q. What's your -- strike that.</p> <p>19 Tell me what expertise you have in FTIR.</p> <p>20 A. In FTIR?</p> <p>21 Q. Yes.</p> <p>22 A. Well, I've published a number of papers</p> <p>23 with FTIR data. We -- we use it quite a bit for</p> <p>24 characterizing the composition of polyurethanes.</p> <p>25 Q. Mm-hmm.</p>
Page 31	Page 33
<p>1 presented this information orally at the meeting?</p> <p>2 A. That's right.</p> <p>3 Q. And you presented it to doctors and</p> <p>4 Ph.D.s?</p> <p>5 A. I presume that's who was in the audience.</p> <p>6 I don't know who was in the audience.</p> <p>7 Q. How long was your presentation?</p> <p>8 A. Oh, I don't know. Something around ten</p> <p>9 minutes. I'm not sure.</p> <p>10 Q. Did you have a PowerPoint presentation</p> <p>11 with your presentation?</p> <p>12 A. I did. And those have been produced. I</p> <p>13 gave them to plaintiff's counsel. It's on the</p> <p>14 drive, I believe.</p> <p>15 Q. Okay. Is that on the thumb drive that we</p> <p>16 have today?</p> <p>17 A. I believe so.</p> <p>18 Q. Thank you.</p> <p>19 Okay. Was Dr. Dunn present for the</p> <p>20 presentation?</p> <p>21 A. No.</p> <p>22 Q. And what was the message you were trying</p> <p>23 to convey to your audience when you made the</p> <p>24 presentation of the information in Exhibit No. 9?</p> <p>25 MR. BOWMAN: Object to form.</p>	<p>1 A. I've also published using FTIR to measure</p> <p>2 the reaction rate of the injectable polypropylene</p> <p>3 grafts that we make. So we follow the isocyanate</p> <p>4 peak over time, fit it to a kinetic model.</p> <p>5 There's a paper I published in 2012 or '13, a few</p> <p>6 years ago, where we used ATR-FTIR to monitor the</p> <p>7 reaction rate.</p> <p>8 Q. Are you trained to perform FTIR analysis</p> <p>9 of fibers, mesh fibers?</p> <p>10 MR. BOWMAN: Object to form.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Could you do it?</p> <p>13 A. I didn't actually do it myself. Dr. Dunn</p> <p>14 did it.</p> <p>15 Q. Are you trained, though, in the use of</p> <p>16 FTIR equipment to conduct analyses of mesh fibers?</p> <p>17 A. I've done it before, not in the last year,</p> <p>18 but as a postdoc I did it.</p> <p>19 Q. Tell me about your experience as a postdoc</p> <p>20 in FTIR analysis.</p> <p>21 A. Well, it was very similar. I mean, when I</p> <p>22 was a postdoc, I did the analysis of -- to</p> <p>23 polyurethanes using FTIR. Now I'm a professor, so</p> <p>24 I have trainees that work for me that do those</p> <p>25 measurements, but I direct them.</p>

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<p>1 Q. Okay. But do you consider yourself 2 qualified to take a piece of polypropylene mesh 3 and conduct an FTIR analysis of it? 4 A. Yes. I've done things like that before. 5 Q. What kind of FTIR machine was used to 6 analyze the mesh in Exhibit No. 9? 7 A. I'm not sure. Dr. Dunn has that 8 instrument in his lab, and I don't know what -- we 9 have a Bruker at Vanderbilt. We've got -- I'm not 10 sure what's in his lab. The one that I use in the 11 Nanoscience Institute I believe was a Bruker. 12 Q. Okay. But you don't know what machine 13 Dr. Dunn used to analyze -- 14 A. I don't know. 15 Q. -- this mesh? 16 A. No. 17 Q. What experience do you have in conducting 18 XPS analysis? 19 A. I've never done XPS analysis. I -- my 20 students have done it under my direction, and 21 I've -- I believe I have some papers with XPS. 22 I'd have to look at my CV. 23 Q. Is it fair to understand that you rely on 24 data generated by XPS as opposed to conducting 25 that kind of testing yourself?</p>	<p>1 talked about it. I just -- I don't know. 2 Q. Do you still have the mesh that you tested 3 as a part of the experimental work in Exhibit 4 No. 9? 5 A. Dr. Dunn, I believe, has that material. 6 Q. Okay. 7 A. It was done through -- he paid for it, so 8 he has the material. 9 Q. Did you talk with Dr. Iakovlev about the 10 results of the testing that you conducted in 11 Exhibit 9? 12 A. I believe we discussed it at the meeting, 13 but I can't remember anything definitive. We 14 talked about, you know -- I don't -- I don't 15 remember. 16 Q. You mentioned before that you published a 17 paper with Dr. Iakovlev? 18 A. That's correct. 19 Q. And Dr. Iakovlev looks at a different 20 methodology for analyzing the extent to which he 21 suggests polypropylene has degraded, correct? 22 A. Dr. Iakovlev uses microscopy. 23 (Marked Exhibit 10.) 24 BY MR. THOMAS: 25 Q. And staining?</p>
Page 35	Page 37
<p>1 A. I've done both. I don't do it, but 2 they're my trainees. They're people that I train, 3 that I pay. 4 Q. I understand. But I'm trying to find out 5 what experience you have, Doctor. 6 A. I mean, I have experience interpreting and 7 working with XPS data. I don't actually do the 8 measurements. 9 Q. Okay. That's fine. 10 A. Okay. Go ahead. Sorry. 11 Q. You have something else you want to say? 12 A. No. I'm -- I'm done. 13 Q. Okay. Do you have continuing experiments 14 with Dr. Dunn? 15 A. Not right -- no, not now. 16 Q. Do you have plans for additional work with 17 Dr. Dunn? 18 A. I don't know. I'm not sure yet. 19 Q. Okay. Since you spoke at the IUGA meeting 20 and this Exhibit 9 was published, have you 21 discussed with Dr. Dunn the contents of the test? 22 A. Since the IUGA meeting? 23 Q. Yes. 24 A. I believe we talked about it some. I 25 can't remember the details. We probably have</p>	<p>1 A. I would -- I would -- yes. 2 Q. Let me show you what's been marked as 3 Deposition Exhibit No. 10 and ask you if 4 Deposition Exhibit No. 10 is the study to which 5 you just referred that you co-authored with 6 Dr. Iakovlev. 7 A. It is. This is the version that's 8 published online on their website. 9 Q. Contents of the article true and accurate 10 to the best of your judgment? 11 A. Yes. 12 Q. And you know that Dr. Iakovlev uses his 13 histological stains in an effort to understand the 14 extent to which polypropylene may have degraded? 15 A. Yes. 16 Q. Do you understand the chemistry by which 17 tissue is stained? 18 MR. BOWMAN: Object to form. 19 THE WITNESS: There's lots of 20 different stains. I mean, is there -- is there 21 something more specific? That's just a really 22 broad question. There's lots of different stains. 23 Are you talking about fixation or staining or what 24 are you -- what are you talking about? 25</p>

10 (Pages 34 to 37)

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<p style="text-align: right;">Page 38</p> <p>1 BY MR. THOMAS:</p> <p>2 Q. I'm talking about how various stains stain</p> <p>3 tissue. Do you know how that works chemically?</p> <p>4 A. Some of them, the ones that I've worked</p> <p>5 with.</p> <p>6 Q. Have you worked with H&E stain before?</p> <p>7 Hematoxylin and eosin?</p> <p>8 A. Mm-hmm, yeah.</p> <p>9 Q. How does hematoxylin and eosin stain</p> <p>10 tissue?</p> <p>11 A. I need to think for a minute.</p> <p>12 MR. BOWMAN: I'm going to object to</p> <p>13 form.</p> <p>14 BY MR. THOMAS:</p> <p>15 Q. Just for the record, you're reading</p> <p>16 through --</p> <p>17 A. I'm looking at the paper.</p> <p>18 Q. -- Exhibit No. 10?</p> <p>19 A. Yeah, I'm looking at the paper.</p> <p>20 Q. I don't want to interrupt you --</p> <p>21 A. Yeah.</p> <p>22 Q. -- but may I ask you a question?</p> <p>23 A. Sure.</p> <p>24 Q. Are you able to tell me, without review of</p> <p>25 Deposition Exhibit No. 10, how hematoxylin and</p>	<p style="text-align: right;">Page 40</p> <p>1 doesn't have the proteins and the...</p> <p>2 Q. Would you expect oxidized polypropylene to</p> <p>3 stain?</p> <p>4 A. No, oxidized polypropylene I would not</p> <p>5 expect to stain.</p> <p>6 Q. Okay. Doctor, let's go back to Exhibit</p> <p>7 No. 9, please.</p> <p>8 A. Okay.</p> <p>9 Unless -- let me go back to my answer. It</p> <p>10 wouldn't -- I need to clarify a point. It</p> <p>11 wouldn't necessarily stain, but the dye could get</p> <p>12 trapped in the pores of a porous material.</p> <p>13 That's -- I need to add that just to be specific.</p> <p>14 Q. And when you say "the dye could get</p> <p>15 trapped in the pores," what do you mean by that?</p> <p>16 You're back referring to the paper again?</p> <p>17 A. Yeah. I need to look at this again. And</p> <p>18 I should state for the record, my main</p> <p>19 contribution to this paper was a myeloperoxidase</p> <p>20 staining.</p> <p>21 So the degraded oxidized polypropylene</p> <p>22 layer is -- it's oxidized. It's a -- it's a</p> <p>23 porous material, and the -- and the dye can get</p> <p>24 trapped in those pores, is the way I understand</p> <p>25 it.</p>
<p style="text-align: right;">Page 39</p> <p>1 eosin stain tissues chemically?</p> <p>2 A. I don't remember the details of it right</p> <p>3 now.</p> <p>4 Q. Do you remember generally how it happens,</p> <p>5 just a general concept? Why hematoxylin stains</p> <p>6 blue and eosin stains pink or red?</p> <p>7 A. I don't remember the reasons for the</p> <p>8 different stains. I know that the nuclei are</p> <p>9 staining blue and the cytoplasm is staining</p> <p>10 pink --</p> <p>11 Q. Is that the --</p> <p>12 A. -- or red.</p> <p>13 Q. Is that the result of a chemical reaction?</p> <p>14 A. I mean, I believe so. It's -- I just</p> <p>15 don't remember the details of that chemical</p> <p>16 reaction.</p> <p>17 Q. Okay. Do you understand that a chemical</p> <p>18 reaction is required in order for a stain to be</p> <p>19 left in tissue?</p> <p>20 A. That's my understanding.</p> <p>21 Q. Okay. Do you know whether polypropylene</p> <p>22 stains?</p> <p>23 A. I wouldn't expect polypropylene to stain.</p> <p>24 Q. Why is that?</p> <p>25 A. Well, it's a synthetic polymer, so it</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. Is that based upon your review of</p> <p>2 Dr. Iakovlev's work?</p> <p>3 A. Yes.</p> <p>4 Q. Do you have any other basis for reaching</p> <p>5 that conclusion, other than your review of</p> <p>6 Dr. Iakovlev's work?</p> <p>7 A. That conclusion is based on my work</p> <p>8 with -- yeah, with Dr. Iakovlev's staining that he</p> <p>9 did in this paper.</p> <p>10 Q. Okay. Now, when you and Dr. Dunn</p> <p>11 performed your study where you intentionally</p> <p>12 oxidized the TVT mesh --</p> <p>13 A. Yes.</p> <p>14 Q. -- did you ever attempt to see if those</p> <p>15 samples would stain?</p> <p>16 A. No.</p> <p>17 Q. Why not?</p> <p>18 A. Because that wasn't the question we were</p> <p>19 trying to answer. We were -- we were answering</p> <p>20 the question can the polypropylene in the mesh</p> <p>21 oxidize, can it degrade. And we assessed</p> <p>22 oxidation by XPS and FTIR. We assessed</p> <p>23 degradation by SEM.</p> <p>24 Q. Did you ever have any conversations with</p> <p>25 Dr. Iakovlev about testing, whether intentionally</p>

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<p>1 oxidized polypropylene would hold stain?</p> <p>2 A. I believe we may have discussed this at</p> <p>3 one point for the paper. I can't remember the</p> <p>4 details, though.</p> <p>5 Q. Did you ever have a discussion about using</p> <p>6 your samples from your test that are contained in</p> <p>7 Exhibit No. 9 to determine whether intentionally</p> <p>8 oxidized polypropylene holds stain?</p> <p>9 A. I don't remember it specifically that way.</p> <p>10 He was -- I believe he was -- I can't remember the</p> <p>11 details, but I believe he was doing his own</p> <p>12 oxidation experiment. And I don't think we were</p> <p>13 going to give him samples. I can't remember,</p> <p>14 though.</p> <p>15 Q. What did -- what do you remember about</p> <p>16 Dr. Iakovlev's own experiment on oxidizing</p> <p>17 polypropylene?</p> <p>18 A. All I remember is that he had some</p> <p>19 samples, and I don't -- I don't -- to my -- I</p> <p>20 don't know that he's tested them. I know that he</p> <p>21 had samples, but I don't know that he ever tested</p> <p>22 them.</p> <p>23 Q. Did you have discussions with Dr. Iakovlev</p> <p>24 about the methodology that you used to conduct the</p> <p>25 test that you and Dr. Dunn conducted there in</p>	<p>1 the lysine-based polyurethane. So I published a</p> <p>2 couple papers on that. That's where I -- that's</p> <p>3 where I got the idea. Now, he may have gotten it</p> <p>4 independently and started before me. I -- I don't</p> <p>5 know that. I don't know when he started it. But</p> <p>6 Dr. Dunn and I did this together independently.</p> <p>7 And I have discussed aspects of it with</p> <p>8 Dr. Iakovlev, but I don't -- I don't remember when</p> <p>9 or what exactly.</p> <p>10 Q. Okay.</p> <p>11 A. Other than what I've told you.</p> <p>12 Q. Do you know why Dr. Iakovlev has not yet</p> <p>13 tested the samples that he is testing now?</p> <p>14 MR. BOWMAN: Object to form.</p> <p>15 THE WITNESS: I don't know. I</p> <p>16 don't -- I don't know what -- he may have tested</p> <p>17 them. I just don't know the status of it.</p> <p>18 (Marked Exhibit 11.)</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. Let me show you what's been marked as</p> <p>21 Deposition Exhibit No. 11. Is Deposition Exhibit</p> <p>22 No. 11 the source document that you used in order</p> <p>23 to determine the methodology for the tests that</p> <p>24 are in Exhibit 9?</p> <p>25 A. It's -- it's a source. There are other --</p>
Page 43	Page 45
<p>1 Exhibit No. 9?</p> <p>2 A. I believe we -- we talked with him about</p> <p>3 that. He was aware of the work. He was aware of</p> <p>4 it, of the -- of the -- you're talking about the</p> <p>5 abstract, right?</p> <p>6 Q. That's correct.</p> <p>7 A. He was aware of that work, yeah.</p> <p>8 Q. Did -- who started their experiments</p> <p>9 first, do you know?</p> <p>10 A. Probably Dr. Iakovlev. He's been working</p> <p>11 on this for some time.</p> <p>12 Q. I'm talking about the intentionally</p> <p>13 oxidized polypropylene experiments now. Do you</p> <p>14 know who did that first?</p> <p>15 A. I don't know. I --</p> <p>16 Q. Before you started your project --</p> <p>17 A. Yeah.</p> <p>18 Q. -- did you start -- did you talk with</p> <p>19 Dr. Iakovlev about it?</p> <p>20 A. I don't -- I don't remember.</p> <p>21 Q. You've been working with Dr. Iakovlev in</p> <p>22 different contexts for a couple years now,</p> <p>23 correct?</p> <p>24 A. Yeah. But I got the idea to do the</p> <p>25 oxidative degradation experiment from my work with</p>	<p>1 like I said, I've published two papers on this,</p> <p>2 which, I mean, I used similar methodology. I'll</p> <p>3 have to look at the details of the medium. I</p> <p>4 can't remember the...</p> <p>5 Q. Well, if you go to page --</p> <p>6 A. So where?</p> <p>7 Q. -- 520 of --</p> <p>8 A. Yeah.</p> <p>9 Q. -- Deposition Exhibit No. 11 --</p> <p>10 A. Okay.</p> <p>11 Q. -- it talks about the in vitro treatments</p> <p>12 with 20 percent hydrogen peroxide solution, .1</p> <p>13 cobalt chloride. Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. Is that the same methodology you used in</p> <p>16 your --</p> <p>17 A. I'm sorry. Where did you read again?</p> <p>18 I'm...</p> <p>19 In vitro treatments, 20 percent peroxide</p> <p>20 with -- I believe it was the same. Let me check</p> <p>21 this abstract. It looks to be the same.</p> <p>22 Q. Okay.</p> <p>23 A. Yeah.</p> <p>24 Q. That's one of the references you cite in</p> <p>25 your abstract?</p>

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<p style="text-align: right;">Page 46</p> <p>1 A. It is, yeah.</p> <p>2 Q. Okay. That's where I concluded that that</p> <p>3 was a source document that you used for your</p> <p>4 methodology; is that fair?</p> <p>5 A. It's a source document. We're pretty</p> <p>6 limited on how many references you can show in an</p> <p>7 abstract. I -- I probably showed this because it</p> <p>8 was the first time this specific medium</p> <p>9 composition was published. That's probably -- but</p> <p>10 I don't remember exactly. But this paper was</p> <p>11 before mine, so that's probably why I cited it in</p> <p>12 the abstract because it was published -- I got the</p> <p>13 idea for my paper from this paper.</p> <p>14 Q. And, Doctor, are you aware of any paper</p> <p>15 that analyzes the extent to which oxidized</p> <p>16 polypropylene will absorb stain?</p> <p>17 A. I don't -- I don't think we're saying that</p> <p>18 oxidized polypropylene absorbs stain. I think</p> <p>19 it -- it gets trapped in the pores. I'm not</p> <p>20 necessarily --</p> <p>21 Q. Okay. Let me ask you that question.</p> <p>22 A. -- saying it absorbs it.</p> <p>23 Q. Let me ask the question that way then.</p> <p>24 A. Okay.</p> <p>25 Q. Well, first of all, is there -- are you</p>	<p style="text-align: right;">Page 48</p> <p>1 pristine mesh will trap stains in the pores such</p> <p>2 that it shows color?</p> <p>3 A. I don't know if that's been done.</p> <p>4 Q. Okay. And it's fair to understand that</p> <p>5 appropriate scientific method would require a</p> <p>6 study intentionally oxidizing polypropylene,</p> <p>7 exposing it to stain, to determine whether it</p> <p>8 does, in fact, get trapped in any cracks, pores,</p> <p>9 or crevasses in order to show color, correct?</p> <p>10 A. I don't know that I would say that. I</p> <p>11 mean, it's -- I don't know how easy it is to do.</p> <p>12 You know, in these previous studies, they -- they</p> <p>13 oxidize -- they oxidize -- okay. I'll be more</p> <p>14 specific.</p> <p>15 In the -- in Exhibit 11 -- and there's an</p> <p>16 earlier -- maybe it wasn't this one. There was an</p> <p>17 earlier paper in '93 where they strained the</p> <p>18 samples and they -- they looked for transverse</p> <p>19 cracks and degradation by SEM, but no one's</p> <p>20 ever -- it might be difficult to do. I wouldn't</p> <p>21 say that it's not scientifically valid because it</p> <p>22 wasn't done. That would give further</p> <p>23 confirmation. But this is a long paper. You just</p> <p>24 don't -- can't -- you know, this was peer reviewed</p> <p>25 and it was published, so I wouldn't say that it's</p>
<p style="text-align: right;">Page 47</p> <p>1 aware of any paper that discusses the absorption</p> <p>2 of stain in oxidized polypropylene?</p> <p>3 A. You say "absorption." You mean like the</p> <p>4 way it would typically work biologically, right?</p> <p>5 Q. Correct.</p> <p>6 A. No, I'm not aware of that.</p> <p>7 Q. Are you aware of any papers which discuss</p> <p>8 the extent to which oxidized polypropylene traps</p> <p>9 stain such that it retains the same and shows</p> <p>10 color?</p> <p>11 A. Well, no, I believe that was the point of</p> <p>12 this study, is to -- I don't believe that's been</p> <p>13 published. I think that was a new finding in this</p> <p>14 study.</p> <p>15 Q. That's Dr. Iakovlev's study?</p> <p>16 A. I'm sorry. Yeah, Dr. Iakovlev's --</p> <p>17 Q. Now, those are --</p> <p>18 A. -- study.</p> <p>19 Q. -- all -- those are all meshes that have</p> <p>20 been explanted from people, correct?</p> <p>21 A. This Dr. Iakovlev study, yes, it's a</p> <p>22 hundred and some patients, yeah.</p> <p>23 Q. And my question is -- I'm referring to</p> <p>24 pristine mesh intentionally oxidized, whether --</p> <p>25 question whether that intentionally oxidized</p>	<p style="text-align: right;">Page 49</p> <p>1 not scientifically valid because it wasn't done in</p> <p>2 vitro.</p> <p>3 Q. Okay. Until you test it, do you have any</p> <p>4 scientific basis to conclude that intentionally</p> <p>5 oxidized polypropylene would, in fact, hold stain</p> <p>6 such that it shows color?</p> <p>7 MR. BOWMAN: Object to form.</p> <p>8 THE WITNESS: If it's -- if it's a</p> <p>9 nanoporous structure, it has porosity, the stain</p> <p>10 could defuse into those pores. And it's not</p> <p>11 necessarily absorbing -- absorbing or reacting</p> <p>12 like it would with tissue, but it -- it would get</p> <p>13 trapped within those pores. But that was just one</p> <p>14 outcome measure. There were others as well. And,</p> <p>15 you know, typically with paper, you try to show it</p> <p>16 multiple -- show the same idea multiple ways, and</p> <p>17 we just didn't do that in vitro experiment in this</p> <p>18 paper.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. I understand.</p> <p>21 Doctor, are you familiar with the process</p> <p>22 whereby tissue is prepared into histological</p> <p>23 slides?</p> <p>24 A. So, yes. So all the -- the bone work that</p> <p>25 I do, I have a woman that does my histology in my</p>

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<p>1 lab. She's my lab manager. And we -- we just</p> <p>2 have some bones that came in just this week. So</p> <p>3 we do micro CT. We keep them in formalin for two</p> <p>4 weeks to fix the tissue, then we have to dehydrate</p> <p>5 it through a series of alcohols. We embed it in a</p> <p>6 polymethyl methacrylate resin, then we grind it</p> <p>7 down to -- cut it, grind it down to 80 microns, do</p> <p>8 different types of stains, do histomorphometry to</p> <p>9 measure the amount of bone graft that's left over.</p> <p>10 So we do this pretty routinely.</p> <p>11 Q. Do you manually prepare your slides or do</p> <p>12 you use a machine?</p> <p>13 A. What do you mean manually prepare them?</p> <p>14 Machine? I'm sorry.</p> <p>15 Q. I'm sorry too. My fault.</p> <p>16 In the preparation of histology slides,</p> <p>17 the way I understand it, it's a very complex</p> <p>18 series of -- of cleanings, washings with xylene,</p> <p>19 alcohol, and water?</p> <p>20 A. It depends on what you're doing, right?</p> <p>21 So for the -- I mean, most of the bone work that I</p> <p>22 do is what we call plastic embedding, hard</p> <p>23 sections. So we don't cut those on a microtome</p> <p>24 like what Dr. Iakovlev did. We have a -- we cut</p> <p>25 them on a band saw, and then we're -- and we glue</p>	<p>1 one that could speak to those details of the</p> <p>2 protocol. I didn't -- I don't have his protocol,</p> <p>3 so I don't know exactly what he did.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. Okay. Going back to Exhibit No. 9, which</p> <p>6 is the presentation you made at the IUGA meeting,</p> <p>7 I want to talk generally about the testing that</p> <p>8 you conducted with Dr. Dunn.</p> <p>9 A. Okay.</p> <p>10 Q. Whose idea was it to conduct that testing?</p> <p>11 A. It was probably both of ours. I -- I knew</p> <p>12 of this oxidative medium that was developed by</p> <p>13 Dr. Jim Anderson in the 1990s. He did some -- so</p> <p>14 I was aware of that in my own research. Like I</p> <p>15 said, I've published a couple papers on it, so I</p> <p>16 knew of the methods. And then I -- we talked with</p> <p>17 Dr. Dunn about how to actually do the experiment.</p> <p>18 Q. Who's "we"? Who talked with Dr. Dunn?</p> <p>19 A. Well, I meant Dr. Dunn and me. I mean, we</p> <p>20 talked --</p> <p>21 Q. Okay. Did you have a -- I'm sorry.</p> <p>22 A. Yeah, we -- we discussed it together.</p> <p>23 Q. Did you have any discussions with</p> <p>24 plaintiff's counsel about conducting these kinds</p> <p>25 of experiments?</p>
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<p>1 them to a surface and we grind them. We grind</p> <p>2 them to 80 microns and we -- and then we stain.</p> <p>3 Q. Are you familiar with the slide</p> <p>4 preparation process used by Dr. Iakovlev in the</p> <p>5 preparation of his slides used in his report,</p> <p>6 Exhibit 10?</p> <p>7 A. I don't know the exact details of how he</p> <p>8 did it, but typically with soft tissue, you can do</p> <p>9 the paraffin embedding, which is using different</p> <p>10 solvents like you described, where you -- you</p> <p>11 still have to dehydrate the tissue. And you --</p> <p>12 but you put it in a softer plastic like paraffin</p> <p>13 so you can cut a thin section on a microtome and</p> <p>14 see different levels of cellular detail.</p> <p>15 Q. And part of that slide preparation process</p> <p>16 involves the washing away of excess stain, doesn't</p> <p>17 it?</p> <p>18 A. I believe so. There's a protocol.</p> <p>19 Q. Do you know how that washing away of</p> <p>20 excess stain would impact the ability of any</p> <p>21 oxidized polypropylene to hold stain, as you've</p> <p>22 postulated?</p> <p>23 MR. BOWMAN: Object to form.</p> <p>24 THE WITNESS: I don't know. Again,</p> <p>25 this is Dr. Iakovlev's work, so he would be the</p>	<p>1 MR. BOWMAN: Object to form.</p> <p>2 THE WITNESS: I don't remember.</p> <p>3 Maybe. I just don't remember what we -- it's been</p> <p>4 a while.</p> <p>5 MR. THOMAS: Okay.</p> <p>6 THE WITNESS: We did it on our own.</p> <p>7 I mean, he paid for it. It was our idea. We did</p> <p>8 it. It was not billed to the litigation.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. I guess my question is, do you recall</p> <p>11 having any conversations with plaintiff's counsel</p> <p>12 about conducting this kind of experiment that's in</p> <p>13 Exhibit No. 9?</p> <p>14 A. I just don't remember. I don't -- I</p> <p>15 don't...</p> <p>16 Q. You talked before about a graduate student</p> <p>17 in your office doing the protocol for the test?</p> <p>18 A. What do you mean by "before"?</p> <p>19 Q. At the Perry deposition.</p> <p>20 A. Yeah. Yeah.</p> <p>21 Q. And how was it that you happened to ask</p> <p>22 your graduate student to prepare the protocol?</p> <p>23 A. Well, she was doing testing for some of</p> <p>24 her materials on the -- I don't remember the</p> <p>25 timing of everything, but she was -- she was</p>

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<p>1 doing -- she was using this medium to test her</p> <p>2 materials as part of her dissertation, and so she</p> <p>3 had access to the material, the medium. And so my</p> <p>4 students, I typically ask them to write what we</p> <p>5 call standard operating procedure, SOP. We -- we</p> <p>6 write those documents for the common procedures</p> <p>7 that we do in the lab, and then I review them and</p> <p>8 approve them. So it was part of her research.</p> <p>9 You know, she was doing research in this area, so</p> <p>10 that's why she was involved, I think. I can't</p> <p>11 remember the details.</p> <p>12 Q. Now, the protocol calls for testing after</p> <p>13 six weeks?</p> <p>14 A. I don't remember.</p> <p>15 Q. Do you remember --</p> <p>16 A. I'd have to look at it. I can't remember</p> <p>17 the timing.</p> <p>18 Q. We'll get to that in a minute.</p> <p>19 Do you remember why you chose the period</p> <p>20 that you did?</p> <p>21 A. You know, I think we probably wanted to --</p> <p>22 we were expecting to see changes within about a</p> <p>23 month, so we figured if we go out six weeks, we</p> <p>24 would see it, I think.</p> <p>25 Q. What kind of changes were you expecting to</p>	<p>1 Q. Now, the simulated in vivo conditions is</p> <p>2 placing pieces of mesh in this medium, correct?</p> <p>3 A. That's right.</p> <p>4 Q. What chemical changes did you find in the</p> <p>5 polypropylene mesh that you tested?</p> <p>6 A. Well, that would be in the -- in the</p> <p>7 figure that's shown here. I'm just trying to</p> <p>8 refresh my memory. But I believe this figure, we</p> <p>9 don't -- let me just make sure that I -- I say it</p> <p>10 correctly. I don't believe this abstract says</p> <p>11 exactly what these data in Figure 1 are for,</p> <p>12 but -- so I don't know if it's TVT or a different</p> <p>13 mesh. But at the zero weeks, we don't really see</p> <p>14 hydroxyl or carbonyl peaks in the IR spectra, and</p> <p>15 at five weeks we do.</p> <p>16 Q. So the first figure on the second page of</p> <p>17 Exhibit 11 is at zero weeks?</p> <p>18 A. Yeah. So if you look on the SEM image, it</p> <p>19 says "zero weeks" in the top left corner. That's</p> <p>20 zero weeks. So there's really no appreciable</p> <p>21 carbonyl or hydroxyl peaks in the IR spectra.</p> <p>22 Q. And so the second figure on the second</p> <p>23 page of Exhibit 9, is that meant to be a</p> <p>24 polypropylene mesh FTIR?</p> <p>25 A. It was not meant to be, it is. So --</p>
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<p>1 see?</p> <p>2 A. Well, changes in the -- in the carbonyl</p> <p>3 and hydroxyl peaks on the surface of the fibers,</p> <p>4 the FTIR. And SEM, you know, looking for</p> <p>5 degradation by SEM. So that's what we were</p> <p>6 expecting to see.</p> <p>7 Q. And did you find changes in the carbonyl</p> <p>8 and hydroxyl peaks for the mesh from the -- strike</p> <p>9 that.</p> <p>10 Did you find changes in the carbonyl and</p> <p>11 hydroxyl peaks consistent with oxidative</p> <p>12 degradation from the TVT mesh that you sampled?</p> <p>13 A. I believe so, but I'd have to look at the</p> <p>14 data again. I mean, this wasn't in my report, so</p> <p>15 I didn't really review any of this stuff.</p> <p>16 Q. Well, let's look at the -- let's look at</p> <p>17 the conclusion of Exhibit No. 9.</p> <p>18 A. Yeah.</p> <p>19 Q. You say here in the conclusion that</p> <p>20 "Oxidative degradation of polypropylene, PP,</p> <p>21 mesh" --</p> <p>22 A. Yeah.</p> <p>23 Q. -- "was evidenced by chemical and physical</p> <p>24 changes under simulated in vivo conditions"?</p> <p>25 A. Mm-hmm.</p>	<p>1 Q. So that's an F -- that's a --</p> <p>2 A. That's an FTIR scan of -- of a</p> <p>3 polypropylene mesh -- I don't know the</p> <p>4 manufacturer -- that was incubated in the</p> <p>5 oxidative medium for five weeks.</p> <p>6 Q. Okay. So the peaks that are shown in the</p> <p>7 second page of Exhibit 9, on the left you circle,</p> <p>8 and it says, "Hydroxyl (OH formation.)"</p> <p>9 What does that show you?</p> <p>10 A. That -- well, that's a -- that's where the</p> <p>11 hydroxyl peak appears in the IR spectra.</p> <p>12 Q. Okay. And that's evidence to you of</p> <p>13 oxidative degradation?</p> <p>14 A. Yes.</p> <p>15 Q. And the second peak marked there is</p> <p>16 carbonyl formation, an arrow and a circle. What</p> <p>17 does that represent?</p> <p>18 A. Well, that's the formation of the carbonyl</p> <p>19 peak in the IR spectra.</p> <p>20 Q. And what you're trying to show to the</p> <p>21 reader of this abstract is that your FTIR data on</p> <p>22 polypropylene pelvic mesh showed these peaks at</p> <p>23 five weeks; is that correct?</p> <p>24 A. Yes.</p> <p>25 Q. And on the right is an image that shows</p>

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<p>1 five weeks. And is that the SEM imaging?</p> <p>2 A. It is.</p> <p>3 Q. And, again, you're trying to show the</p> <p>4 readers that at five weeks that the polypropylene</p> <p>5 mesh that you tested looked like this under SEM?</p> <p>6 A. That's right.</p> <p>7 Q. Okay.</p> <p>8 MR. THOMAS: Let's go off the record.</p> <p>9 I need to take a break, please.</p> <p>10 (Brief recess observed.)</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Doctor, going back to Exhibit No. 9, those</p> <p>13 images at the end that we've just been talking</p> <p>14 about --</p> <p>15 A. Yeah.</p> <p>16 Q. -- where you identified for me the FTIR,</p> <p>17 the polypropylene mesh, what's your basis for your</p> <p>18 understanding that the peak on the left is -- I</p> <p>19 think you called it -- is that hydroxyl? Is that</p> <p>20 the word you used?</p> <p>21 A. Hydroxyl peak.</p> <p>22 Q. And the peak on the right, I think we</p> <p>23 called it a carbonyl peak; is that correct?</p> <p>24 A. Yes.</p> <p>25 Q. What references did you use in order to</p>	<p>1 I mean, I know there's references on this. I -- I</p> <p>2 don't remember exactly which specific one. I</p> <p>3 mean, they're probably cited in some of my papers.</p> <p>4 Q. Okay. And do you remember presenting</p> <p>5 these slides as a part of your presentation?</p> <p>6 A. Well, it wasn't this -- I mean, you have</p> <p>7 the slides, so it was -- it was similar. It was</p> <p>8 FTIR data and SEM data. That's what I showed. I</p> <p>9 didn't present the XPS. Just a FTIR and the SEM</p> <p>10 is what I showed.</p> <p>11 Q. Okay. Let's go back to the first page of</p> <p>12 Exhibit No. 9, down under "Results."</p> <p>13 A. Okay.</p> <p>14 Q. And midway through that paragraph it says,</p> <p>15 "The dramatic increase in the size of the dash OH</p> <p>16 and C" -- I think that's called --</p> <p>17 A. That's the carbonyl.</p> <p>18 Q. "Double -- double bond O peaks from four</p> <p>19 (not shown) to five weeks is indicative of</p> <p>20 chemical induction."</p> <p>21 And what you're referring to is the --</p> <p>22 again, that image on the page 2 of Exhibit No. 9?</p> <p>23 A. Yeah. I'm going from memory because this</p> <p>24 wasn't in my report, and I'm not relying on it in</p> <p>25 this case. But, I mean, what -- what I remember</p>
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<p>1 understand that?</p> <p>2 A. I -- I don't remember right now. The --</p> <p>3 there are tables that list where these different</p> <p>4 peaks occur in materials. I don't remember</p> <p>5 exactly which reference we used. I mean, this</p> <p>6 is...</p> <p>7 Q. I know very little about FTIR. What I do</p> <p>8 know is that there are standards or tables that</p> <p>9 you look at --</p> <p>10 A. Right.</p> <p>11 Q. -- in order to identify different kinds of</p> <p>12 levels within the FTIR, correct?</p> <p>13 A. Right.</p> <p>14 Q. And do you recall as you sit here today</p> <p>15 what you consulted in order to understand what</p> <p>16 those peaks meant?</p> <p>17 A. The specific reference?</p> <p>18 Q. Yes.</p> <p>19 A. I don't remember the specific reference</p> <p>20 that we used. I mean, Dr. Dunn I know has</p> <p>21 references on these. I guess I've just been doing</p> <p>22 it so long, I just know that that's where hydroxyl</p> <p>23 shows up. And that's -- carbonyl's in the 16,</p> <p>24 1700 inverse centimeters range, and this</p> <p>25 hydroxyl's in this 34, 3500. It's a broader peak.</p>	<p>1 is that the -- the -- the peaks up to about three</p> <p>2 or four weeks were really negligible. And then it</p> <p>3 just says here, four to five weeks, we saw a</p> <p>4 substantial bump. And this is what's referred to</p> <p>5 in Liebert's previous paper about induction, where</p> <p>6 you have a substantial increase in the amount of</p> <p>7 carbonyl and hydroxyl groups on the surface.</p> <p>8 That's where -- the basis of that statement.</p> <p>9 Q. I don't want to go into great detail on</p> <p>10 that --</p> <p>11 A. No, I know. Yeah.</p> <p>12 Q. -- because I don't want to replot this</p> <p>13 ground.</p> <p>14 A. Yeah, I understand.</p> <p>15 Q. But chemical induction is -- is basically</p> <p>16 the tipping point, isn't it?</p> <p>17 A. Tipping point? It becomes autocatalytic.</p> <p>18 Is that what you mean?</p> <p>19 Q. Is that how you'd describe it?</p> <p>20 A. That's how I would -- I mean, it -- my</p> <p>21 understanding is that you get so many hydroxyl and</p> <p>22 carbonyl groups on the surface that they --</p> <p>23 they -- they just -- they start catalyzing this</p> <p>24 reaction and it becomes much faster, so you start</p> <p>25 forming more at a faster rate. That's the idea of</p>

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<p>1 induction that's --</p> <p>2 Q. And at that point --</p> <p>3 A. -- taught by Liebert and others.</p> <p>4 Sorry.</p> <p>5 Q. My fault.</p> <p>6 And at that point, you would lead to the</p> <p>7 embrittlement, cracking, and failure?</p> <p>8 A. Yes. Once it becomes induced, then</p> <p>9 degradation sets in. Embrittlement, cracking,</p> <p>10 those are all the things that are discussed in the</p> <p>11 report.</p> <p>12 Q. And why did you stop at this point? Why</p> <p>13 didn't you continue testing?</p> <p>14 MR. BOWMAN: Object to form.</p> <p>15 THE WITNESS: I don't remember the</p> <p>16 details, but we just didn't have that many</p> <p>17 samples. We were limited on samples. We had an</p> <p>18 exemplar. We didn't have a lot of material. We</p> <p>19 wanted to have replicates. We expected to see</p> <p>20 oxidation within a month, so we didn't want to</p> <p>21 miss it, so we sampled weekly. And we just didn't</p> <p>22 have that much material. That's what I remember,</p> <p>23 but, again, I haven't reviewed these documents</p> <p>24 because it's not part of my -- it's not part of my</p> <p>25 report.</p>	<p>1 on them?</p> <p>2 MR. THOMAS: Well, it's not a Bates.</p> <p>3 It's just a number. Whether that's a -- I guess</p> <p>4 that qualifies as a Bates. Just so I can call out</p> <p>5 a page number and make a better record of what</p> <p>6 he's looking at.</p> <p>7 (Marked Exhibit 13.)</p> <p>8 MR. THOMAS: Fair enough?</p> <p>9 MR. BOWMAN: Yes. But I need to</p> <p>10 object as -- you know, this isn't part of his</p> <p>11 report, and we do have a lot to get through,</p> <p>12 but...</p> <p>13 MR. THOMAS: Oh, we'll have plenty of</p> <p>14 time today.</p> <p>15 MR. BOWMAN: Yeah.</p> <p>16 MR. THOMAS: I'm not worried about</p> <p>17 finishing today on time. Matter of fact, I'm</p> <p>18 hoping to catch an earlier flight.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. Let's go to page 11, please. Page 11,</p> <p>21 does that show one of the vials with the mesh in</p> <p>22 the oxidative medium?</p> <p>23 MR. BOWMAN: Object to form.</p> <p>24 THE WITNESS: That's what it appears</p> <p>25 to be.</p>
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<p>1 (Marked Exhibit 12.)</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. Doctor, I'm going to hand you what I've</p> <p>4 marked as Exhibit No. 12. And Exhibit No. 12 is a</p> <p>5 set of the documents that you produced to us in</p> <p>6 the Perry case --</p> <p>7 A. Yeah.</p> <p>8 Q. -- and which I assume to be a complete set</p> <p>9 of what is on that link that I've just received.</p> <p>10 The only thing that's different about</p> <p>11 these documents is that we've numbered them so</p> <p>12 that they're available for easier reference. What</p> <p>13 you supplied to us was not numbered, and so we've</p> <p>14 had them numbered sequentially from 1 up to 214.</p> <p>15 And I want to ask you some questions about these</p> <p>16 documents.</p> <p>17 A. I mean...</p> <p>18 MR. BOWMAN: How did you say they</p> <p>19 were numbered? You just put them in the same</p> <p>20 number that they were given to you in the folders?</p> <p>21 MR. THOMAS: We received them</p> <p>22 electronically, and then we just numbered them</p> <p>23 sequentially as we received them. See the lower</p> <p>24 right-hand number?</p> <p>25 MR. BOWMAN: Mm-hmm. You put a Bates</p>	<p>1 BY MR. THOMAS:</p> <p>2 Q. Okay. And take your time looking through</p> <p>3 this as you want to. I know you haven't seen it</p> <p>4 in a while. I -- the first several pages were</p> <p>5 just a bunch of empty vials, and that's why I</p> <p>6 didn't ask you any questions about those. Those</p> <p>7 are you photographing all of the vials that -- --</p> <p>8 A. I mean, this --</p> <p>9 Q. -- you used?</p> <p>10 A. -- is all Dr. Dunn's work, so I -- you</p> <p>11 know, I -- I don't know exactly what he did here</p> <p>12 because I didn't review it for this. So, I mean,</p> <p>13 these all look like vials that he used for the</p> <p>14 experiment and took a picture of.</p> <p>15 Q. Okay.</p> <p>16 MR. BOWMAN: Yeah, and that's part of</p> <p>17 my objection to the document, is that, you know,</p> <p>18 he's already testified that he didn't take these</p> <p>19 pictures, that this wasn't --</p> <p>20 MR. THOMAS: That's fine.</p> <p>21 MR. BOWMAN: -- actually produced.</p> <p>22 I think it was produced in -- in --</p> <p>23 MR. THOMAS: In Perry.</p> <p>24 MR. BOWMAN: -- the Perry case.</p> <p>25 But I don't know that he can</p>

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<p>1 authenticate a single document in here. I don't 2 know any of that. 3 MR. THOMAS: Well -- 4 MR. BOWMAN: And, honestly, I don't 5 know the paging numbers or the system that -- 6 MR. THOMAS: Well, I -- your 7 objection's preserved. If he can answer the 8 questions, great. If he can't -- 9 MR. BOWMAN: Great. 10 MR. THOMAS: -- that's fine too. 11 MR. BOWMAN: Thank you. 12 BY MR. THOMAS: 13 Q. On page 13. 14 A. Okay. 15 Q. Page 13 is a container labeled "AT 16 oxidative media 9." I think that's 16/14, almost 17 a year ago today. 18 A. Okay. 19 Q. Do you recognize that as being the media 20 that was used? 21 A. I don't know. I mean, I didn't do this. 22 So it's -- the medium has this kind of color. 23 Q. Okay. 24 A. Where this came -- I don't -- I can't 25 really say. I don't know.</p>	<p>1 these vials. I don't know. I can't explain these 2 things. 3 Q. All right. Now, if you go to page 25, 4 page 25 shows what? 5 A. So the -- the PP standard, I believe -- 6 but, I mean, this is an incomplete document, so, I 7 mean, I don't have the whole thing. But I -- it 8 may be what he was -- it looks like what he was 9 calling is the -- is the polypropylene standard 10 that didn't have stabilizer in it. 11 Q. Okay. 12 A. That's what I believe that is, but I don't 13 know. 14 Q. And we get back there and we have all the 15 other documents, I think that confirms that, but 16 I -- 17 A. Okay. 18 Q. I thought you -- I think that's exactly 19 right. 20 A. All right. 21 Q. And so the bottle on the left which has 22 the number 68 at the top is a container of the 23 unstabilized polypropylene? 24 A. I believe that's what it is, but... 25 Q. And the vials that are off to the right,</p>
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<p>1 Q. On the left is "AT." Do you know what the 2 AT is? Is that the initials of the graduate 3 student? 4 A. Those are her initials. 5 Q. Do you know if that's why that notation is 6 there? 7 A. I have no idea why it's there. 8 Q. On the bottom of that bottle is a white 9 thing. Do you know what the white thing is? 10 A. Again, I don't know because I didn't 11 actually make this, but it appears to be -- it 12 might be a magnetic stir bar. I don't know. 13 Q. Okay. 14 A. With a Teflon coating. I don't -- that's 15 what you'd typically use. 16 Q. On page 15, 15 shows a series of these 17 containers with what appears to be oxidative media 18 with pieces of TVT in them. Is that what you 19 recollect to be part of the experiment? 20 A. That's what it appears to be. 21 Q. Okay. And then you go to page 17. 22 Page 17 shows the bottles, and it has three -- 23 one, two, three are empty. Do you know why those 24 three are empty? 25 A. Again, I did not take these pictures, make</p>	<p>1 the six of them, are the unstabilized 2 polypropylene in the oxidative medium; is that 3 correct? 4 A. I believe so. Again, I didn't do this, 5 so -- 6 Q. Okay. 7 A. -- I'm speculating. 8 Q. And if you go to page 40, do you see 9 page 40? This is the first FTIR. What do you 10 call this? A spectra or spectrum? What's the 11 right word to used? 12 A. This would be an FTIR spectrum. 13 Q. Okay. The FTIR spectrum up in the upper 14 left-hand corner is identified as No. 10. Do you 15 know what happened to weeks 1 through 9 -- excuse 16 me. 17 Do you know what happened to FTIRs 18 1 through 9? 19 A. No. Again, this is Dr. Dunn's data, so I 20 don't -- I don't -- I don't know. 21 Q. We talked before about standards that 22 people use when they do FTIR where they compare 23 their spectra to a library standard or to an 24 industry standard to see how it matches with that 25 library standard. Are you familiar with that</p>

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<p>1 process?</p> <p>2 A. Yeah, I'm familiar with that.</p> <p>3 Q. Do you know whether Dr. Dunn did that in</p> <p>4 this case?</p> <p>5 A. I don't know.</p> <p>6 Q. Did you have discussions with Dr. Dunn</p> <p>7 about that?</p> <p>8 A. I don't remember the discussions with</p> <p>9 Dr. Dunn. I...</p> <p>10 Q. As you look at the upper-hand left, this</p> <p>11 is the PP standard 1. So this is going to be the</p> <p>12 unstabilized polypropylene, correct?</p> <p>13 A. I believe so.</p> <p>14 Q. All right. And as I look at the</p> <p>15 spectra -- spectrum, it shows two peaks, one at</p> <p>16 2800 to 3000 and one at about 1300 to 1500. What</p> <p>17 does that tell you?</p> <p>18 A. Well, I mean, I believe those are peaks</p> <p>19 associated with the structure of polypropylene.</p> <p>20 But I don't -- I don't remember the actual bonds</p> <p>21 they represent. I'd have to look at those. I</p> <p>22 don't remember that.</p> <p>23 Q. There's a peak that appears right around</p> <p>24 23 -- excuse me, 22 to 24. Do you know what that</p> <p>25 represents?</p>	<p>1 of a TVT sample at week zero, correct?</p> <p>2 A. That's what it says.</p> <p>3 Q. Okay. If you look at the difference</p> <p>4 between pages 42 and 43, there's a -- a</p> <p>5 significant peak at about 2300 in run 2 that is</p> <p>6 not present in run 1. Do you know what that peak</p> <p>7 is on -- in FTIR 13 for run 2? Do you know where</p> <p>8 that is and what that indicates?</p> <p>9 A. I said before I have to look -- look up</p> <p>10 what bonds are absorbing in that. I don't</p> <p>11 remember the -- the bond that absorbs at that wave</p> <p>12 number. I'd have to look at it.</p> <p>13 Q. Do you know why there's a differences</p> <p>14 between what is the same sample run at different</p> <p>15 times?</p> <p>16 A. No. I didn't run the samples, so I -- I</p> <p>17 mean, this is somebody -- this is Dr. Dunn's --</p> <p>18 Q. Is the --</p> <p>19 A. -- data.</p> <p>20 Q. -- difference -- I'm sorry. Go ahead.</p> <p>21 A. I mean, it's his data. I don't -- I don't</p> <p>22 know.</p> <p>23 Q. Is the difference in the peak that appears</p> <p>24 in image 13 compared to image 12 evidence of</p> <p>25 contamination of the sample?</p>
Page 71	Page 73
<p>1 A. I can't remember. I'd have to look at it.</p> <p>2 Q. And the reason why I ask is, if you go to</p> <p>3 the next page, and you go to a standard</p> <p>4 polypropylene sample, it doesn't have that peak.</p> <p>5 Any explanation for why those peaks are different,</p> <p>6 even though it's a standard that's tested at week</p> <p>7 zero?</p> <p>8 A. I mean, I don't remember. I haven't</p> <p>9 reviewed this. I don't -- I don't remember.</p> <p>10 Q. Well, as a person who conducts FTIR, do</p> <p>11 you have an explanation for -- for why two samples</p> <p>12 of the same material would have different FTIR at</p> <p>13 the same time?</p> <p>14 A. I'd have to look at the details. I</p> <p>15 don't -- I don't --</p> <p>16 Q. What other details would you have to use,</p> <p>17 look at?</p> <p>18 A. I'd have to look at what other peaks show</p> <p>19 up in that wavelength. I mean, I just -- I'd have</p> <p>20 to review it. I don't have all those things</p> <p>21 memorized. I mean, it's --</p> <p>22 Q. Okay.</p> <p>23 A. -- a lot of different...</p> <p>24 Q. Let's look at pages 42 and 43. 42 and 43</p> <p>25 are FTIRs 12 and 13. And they are run 1 and run 2</p>	<p>1 A. I don't know. I don't -- I didn't do it.</p> <p>2 Q. Let's go to page 52. Page 52 is week --</p> <p>3 week 1, TVT 5. That would be the sample number</p> <p>4 for the TVT, correct?</p> <p>5 A. That's right.</p> <p>6 Q. Run No. 2. So a week into it, you see a</p> <p>7 peak again at around 2350 that goes straight down.</p> <p>8 What's going on there?</p> <p>9 A. You're focusing on the wrong peaks. I'll</p> <p>10 just say that, but...</p> <p>11 Q. Well --</p> <p>12 A. So -- okay. I didn't do this work. It's</p> <p>13 uncomfortable being deposed on something that</p> <p>14 wasn't in my report, I wasn't really prepared to</p> <p>15 review, and I just had a document thrust in front</p> <p>16 of me with no references to check. But I know</p> <p>17 there can -- we typically purge these things with</p> <p>18 nitrogen, and there can be some carbon dioxide.</p> <p>19 This -- this might be in that range because when</p> <p>20 we do the urethane reactions, there's a big NCO</p> <p>21 peak at 2200 inverse centimeters, and we watch the</p> <p>22 size of that peak decrease. And we have to be</p> <p>23 careful sometimes about -- it could be -- I think</p> <p>24 it might be background CO2 that's shifting that up</p> <p>25 and down. It looks like it's in that same range,</p>

19 (Pages 70 to 73)

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<p>1 but I'm speculating. I have to check my 2 references. But I know we sometimes have to make 3 corrections if it's not completely purged. 4 Q. What do you do to make corrections? How 5 do you do that? 6 A. Well, when you integrate the peak areas, 7 which we didn't do in this study, but when 8 you're -- when you're tracking an NCO reaction and 9 the -- you're watching the NCO peak decrease -- 10 I'm just going to pull out my paper because this 11 may take a little while. Let me find my -- I 12 wonder if it's in here. It may not be. Let's 13 see. 14 On page 42 of my CV is where we studied 15 the reactivity of these injectable polyurethanes, 16 and we're still doing this work. And if we want 17 to measure a reaction rate constant, you have to 18 measure the rate of disappearance of that peak, 19 and so we have to do baseline corrections. It's 20 an established thing that's done. You do a 21 baseline correction to correctly integrate the 22 area under those peaks. And I think this is 23 like -- has something to do with the carbon 24 dioxide that may be in the -- in the environment 25 if it's not completely purged with nitrogen, but I</p>	<p>1 that appears on the right at around between 1500 2 and 1800 is a carbonyl peak? Is that what your 3 testimony is? 4 A. Wait a minute. I need to look. I need to 5 look for a minute. This isn't a memory test. 6 Q. It's at week 1. 7 A. You know, I -- I really -- I'm 8 uncomfortable -- you're just, like, turning the 9 pages in this document. If we're going to go 10 through this document, I need some time to sit 11 down and look at it because I feel like I'm being 12 ambushed here. I'm trying to -- you're trying to 13 trap me or catch me in saying something. I need 14 some time to review this because it's not on my 15 reliance list -- I mean it's not in my report. I 16 didn't come here prepared to talk about this. We 17 didn't produce this as evidence. And this is the 18 first time I've seen this. I need some time to go 19 through it and refresh myself with it because I 20 don't think it's fair to just have to go through 21 page by page, tell me what this peak is, tell me 22 what this peak is. I need to have to be able to 23 review that. 24 Q. Let me ask you this, Doctor. I'll stop 25 doing that except for a couple, and we'll talk</p>
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<p>1 can't remember the details. But I have seen this 2 type of thing before where it can flip up or down 3 and -- but it doesn't have anything to do with a 4 carbonyl or a -- or a hydroxyl group. It's -- 5 but, again, I'd have to... 6 Q. Okay. On the right at about 1600 there's 7 another peak that wasn't there before. What is 8 that? And I'm referring now to FTIR 34 -- 9 A. Yeah. 10 Q. -- on page 52 of Exhibit 12. 11 A. I'd say it's about 1650. And this is 12 consistent with some -- I'm just going to have to 13 go to some Ethicon documents here, so it's going 14 to take me a few minutes. If you want to go 15 through these spectra like this, I need some time 16 to -- because I wasn't prepared for it. 17 Q. Do you know what this peak is as you look 18 at it? 19 A. It's -- I believe it's the carbonyl. But 20 I'm going to give you some exact peak numbers that 21 were reported in Ethicon documents for -- for 22 carbonyls, aldehydes, ketones that can form on 23 polypropylene when it's being oxidized. 24 Q. Okay. You can do that if you like. But 25 do you know as you sit here today whether the peak</p>	<p>1 about them here in a second. 2 A. Okay. 3 Q. I won't put you through this. But if you 4 look on the upper left-hand corner of these FTIR 5 spectra, you see identifying numbers, correct? 6 A. What do you mean "identifying"? 7 Q. PCT-168. See that? 8 A. Okay. 9 Q. What does that mean? 10 A. I don't know. You'd have to ask Dr. Dunn. 11 That's a number that he -- 12 Q. Assigned to the test? 13 A. I assume, but I don't -- I don't know. 14 You have to ask Dr. Dunn why that says PCT-168. I 15 didn't write that. 16 Q. Okay. And as you look over, you see the 17 FTIR, and that's the number of the image, correct? 18 A. I don't know. It says 0034. I don't know 19 what that number is. 20 Q. Well, then it says -- after 0034, it says 21 what week the test was run, correct? 22 A. It says week 1, so I'm assuming that was 23 the week 1 sample. 24 Q. And TVT 5 would be the TVT 5 sample 25 number, correct?</p>

20 (Pages 74 to 77)

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<p style="text-align: right;">Page 78</p> <p>1 A. I don't know.</p> <p>2 Q. That's the bottle which we looked at a</p> <p>3 minute ago with the number on it?</p> <p>4 A. It could be, but I don't know. This is --</p> <p>5 Q. Do you have any other explanation for it?</p> <p>6 A. I said I don't know.</p> <p>7 MR. BOWMAN: Object to form.</p> <p>8 THE WITNESS: I don't know.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. And run No. 2 means it's the second run on</p> <p>11 that sample, correct?</p> <p>12 A. I don't know. I don't know what any of</p> <p>13 this means. I didn't write it.</p> <p>14 MR. BOWMAN: Just for the sake of</p> <p>15 trying to clear something up, I can -- I can</p> <p>16 stipulate that PCT-168 is how Dr. Dunn recognized</p> <p>17 his work done in the Ethicon litigation.</p> <p>18 MR. THOMAS: Thank you.</p> <p>19 MR. BOWMAN: Okay.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. Let me go to page 78, please.</p> <p>22 A. I thought we were done with this.</p> <p>23 Q. I said I needed to ask you a couple of</p> <p>24 questions.</p> <p>25 A. Well, then I need to review this stuff.</p>	<p style="text-align: right;">Page 80</p> <p>1 which one of these spectra it is. But I'm not</p> <p>2 just going to look at a picture in this book you</p> <p>3 just gave me and a small picture from an abstract</p> <p>4 and say. I don't know. I need to review that.</p> <p>5 Q. Doctor, I'm not going to argue with you.</p> <p>6 I hear what you're saying, and I'll stop asking</p> <p>7 questions. But for the record --</p> <p>8 A. Well, you said that five minutes ago.</p> <p>9 Q. Excuse me. Excuse me. For the record,</p> <p>10 these are documents that you produced to us both</p> <p>11 in the Perry case and today by a link, and so I --</p> <p>12 I -- I was hoping that we could answer questions</p> <p>13 about them and -- we'll just have to come back</p> <p>14 later.</p> <p>15 A. That was the Perry case. This is a</p> <p>16 different case. These documents weren't...</p> <p>17 Q. They weren't available in the Perry case</p> <p>18 because you gave them on a thumb drive and we</p> <p>19 didn't have them to put -- --</p> <p>20 A. They were --</p> <p>21 Q. -- in front of you. They were on a thumb</p> <p>22 drive.</p> <p>23 A. They were on a thumb drive -- I don't want</p> <p>24 to get angry, but he spent two hours going through</p> <p>25 this with me, and I told him the same thing. If</p>
<p style="text-align: right;">Page 79</p> <p>1 Q. Just -- I'm just -- this is the image that</p> <p>2 appears in your report, in your publication. Are</p> <p>3 you not going to answer the questions about it?</p> <p>4 A. Is this for Exhibit 9?</p> <p>5 Q. Yes.</p> <p>6 A. I mean, I need time to review it. I mean,</p> <p>7 I didn't really look at this because it wasn't</p> <p>8 even part of the report. I mean, it's -- I don't</p> <p>9 understand the purpose of this. I mean...</p> <p>10 Q. Doctor, if you're not going to answer the</p> <p>11 question, you tell me, and we'll be fine with it.</p> <p>12 If you tell me no, then it's no, and I can move</p> <p>13 on.</p> <p>14 A. I can't -- I need time to look at it. I'm</p> <p>15 not going to answer yes or no without time. You</p> <p>16 put these two things in front of me that I haven't</p> <p>17 really looked at for months and ask me -- I don't</p> <p>18 know. I need -- I need time to look at it and</p> <p>19 think. I can't just...</p> <p>20 Q. Can you look at the image on page 78,</p> <p>21 which is FTIR 78, week 5, TVT 28, run 1, and tell</p> <p>22 me if that's the same image that appears in</p> <p>23 Exhibit No. 9?</p> <p>24 A. I can't tell that it is or it isn't. I'd</p> <p>25 have to confirm with Dr. Dunn where that image --</p>	<p style="text-align: right;">Page 81</p> <p>1 you want to know about these documents, you have</p> <p>2 to depose Dr. Dunn because I didn't do these</p> <p>3 measurements, I didn't write these spectra. I</p> <p>4 didn't do it. I got data from Dr. Dunn for -- for</p> <p>5 this abstract, but I don't know what the source</p> <p>6 data is. He's the one that knows all of that. I</p> <p>7 said that in Perry. Nobody wanted to depose</p> <p>8 Dr. Dunn. So I don't understand why we're doing</p> <p>9 this again. It's a rerun.</p> <p>10 Q. Okay. Let's go to page 188, please.</p> <p>11 Pages 187 and 188 of Exhibit No. 12 are a report</p> <p>12 dated November the 6th, 2014, from Professor</p> <p>13 Bridget Rogers to -- to Russell Dunn. You've seen</p> <p>14 that before, correct?</p> <p>15 A. Yes.</p> <p>16 Q. Are you able to answer questions about the</p> <p>17 findings on page 188 of Exhibit No. 12? The XPS</p> <p>18 findings?</p> <p>19 A. No. I didn't review it. I need -- if</p> <p>20 we're going to talk about that, I need a break to</p> <p>21 review these. I will answer them if I have time</p> <p>22 to review them, but I'm not going to answer them</p> <p>23 right now. I need time to review it. This was</p> <p>24 not -- I'm not relying on this for this case. It</p> <p>25 was produced in Perry. It wasn't brought up in</p>

21 (Pages 78 to 81)

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<p>1 trial. No deposition of Dr. Dunn was taken. So I</p> <p>2 don't understand why I'm being asked these</p> <p>3 questions again. It doesn't seem reasonable to</p> <p>4 me. And if you want to ask me about it, I need</p> <p>5 time to look through this book, look through my</p> <p>6 notebook. I can write down -- write down all the</p> <p>7 peak numbers and -- and give you a story, but it's</p> <p>8 going to take me a couple of hours to do that.</p> <p>9 And I don't -- I don't know that you want to do</p> <p>10 that today.</p> <p>11 Q. Well, I don't want to waste my time or</p> <p>12 your time.</p> <p>13 A. I live here. I'm here all day til 5:30,</p> <p>14 so we can do it if you want to. But I don't want</p> <p>15 you to be trying to give the impression that I</p> <p>16 don't know how to read FTIR spectra just by</p> <p>17 putting a book in front of me that I haven't seen.</p> <p>18 Q. Please don't read anything into my</p> <p>19 questions. I'm just asking --</p> <p>20 A. Well, that's the way it comes across. I'm</p> <p>21 sorry, but --</p> <p>22 Q. Well, that's not my intention.</p> <p>23 Let me ask you this question. Are you</p> <p>24 able, without spending a couple hours going</p> <p>25 through this information as you've just described,</p>	<p>1 Hernia Meshes from an Individual Patient."</p> <p>2 Have you seen that before?</p> <p>3 A. Yes.</p> <p>4 Q. If you go to page 1117 of Exhibit No. 13,</p> <p>5 are you familiar with this in Figure 3, the</p> <p>6 ATR-FTIR scan?</p> <p>7 A. Yes.</p> <p>8 Q. And do you see there the indication</p> <p>9 that -- the carbonyl peak at 1740?</p> <p>10 A. Yes.</p> <p>11 Q. And you understand that Wood concludes in</p> <p>12 this article that the carbonyl peak at 1740 is</p> <p>13 indicative of polypropylene oxidation and</p> <p>14 degradation?</p> <p>15 A. That's his conclusion, I believe.</p> <p>16 Q. Do you agree with that?</p> <p>17 A. Yes.</p> <p>18 Q. Is -- is that the best evidence that you</p> <p>19 know of of oxidative degradation and a carbonyl</p> <p>20 peak at 1740?</p> <p>21 MR. BOWMAN: Object to form.</p> <p>22 THE WITNESS: No. As I was saying</p> <p>23 earlier, these peaks can shift. I mean, and</p> <p>24 Dr. Burkley has some notes where he talks about</p> <p>25 ketoesters, sugar-like species, acrylic species</p>
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<p>1 to tell me what it is about the data in Exhibit</p> <p>2 No. 12 that you believe shows that</p> <p>3 polypropylene -- excuse me, that Ethicon TVT mesh</p> <p>4 underwent oxidative degradation that's indicative</p> <p>5 of chemical induction? Are you able to do that</p> <p>6 without spending the time looking at the report?</p> <p>7 MR. BOWMAN: Object to form.</p> <p>8 THE WITNESS: I'm not willing to do</p> <p>9 that without reviewing these documents because I</p> <p>10 did not rely upon them for my opinions.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Okay. It's not my intention to aggravate</p> <p>13 you or frustrate you. It is my intention to get</p> <p>14 the best answers I can based on the information I</p> <p>15 do -- I'm not going to argue with you.</p> <p>16 A. I don't want to argue either, but I -- I'm</p> <p>17 just not prepared. I didn't rely on them.</p> <p>18 They're not in my report. If you want to ask me</p> <p>19 questions about it, I need time to review it. I</p> <p>20 think that's reasonable.</p> <p>21 Q. Okay. Doctor, I'm going to hand you now</p> <p>22 what's been marked as Deposition Exhibit No. 13.</p> <p>23 Deposition Exhibit No. 13 is a study titled</p> <p>24 "Materials Characterization and Histological</p> <p>25 Analysis of Implanted Polypropylene, PTFE, and PET</p>	<p>1 that have absorptions in the 16 to 1700 inverse</p> <p>2 centimeters. So -- so the peaks can shift.</p> <p>3 It's -- it's...</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. Do you --</p> <p>6 A. It's the nature of the work.</p> <p>7 Q. Okay. Do you know whether Dr. Burkley is</p> <p>8 correct? Do you have any independent knowledge of</p> <p>9 these peaks to know whether Dr. Burkley is correct</p> <p>10 in those documents?</p> <p>11 MR. BOWMAN: Object to form.</p> <p>12 THE WITNESS: Others cite these</p> <p>13 ranges as well. You can see these carbonyl</p> <p>14 species in the 1600s, you can see them in the 17.</p> <p>15 Urethane carbonyl we see in my materials at 1720,</p> <p>16 1730 inverse centimeters. But they -- they can --</p> <p>17 they can shift depending on -- it's just -- that's</p> <p>18 just the nature. It's a complex reaction, and</p> <p>19 there's lots of species that are formed.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. So of what benefit to you is FTIR if these</p> <p>22 numbers can shift?</p> <p>23 A. Well, you're not going to see -- I mean,</p> <p>24 if you -- the standard poly -- the pure</p> <p>25 polypropylene that's not been oxidized is not</p>

22 (Pages 82 to 85)

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<p>1 going to show those peaks at those wave numbers. 2 It's going to be, you know, the -- the ones that 3 we saw in that book you were showing me, more 4 1500. You're not going to see this broad peak at 5 3400 and you're not going to see this carbonyl 6 peak because if it doesn't have any oxygen, you're 7 just not going to see anything there. When you 8 start seeing peaks show up in that region, that 9 tells you that there's oxidation. 10 Q. What's the peak for DLTDP? 11 A. I don't remember. I'd have to look at -- 12 Dr. Burkley had some comments on that. It may 13 have been in that 1740 region. I'd have to look. 14 Q. That's fine. 15 A. Well, okay. I found the document, 16 actually. So Mr. Burkley says that there is a 17 1740 inverse centimeter band due to the -- the 18 DLTDP antioxidant. 19 Q. Okay. 20 A. In the -- 21 Q. I'm sorry. 22 A. In the eight-year sample spectra, he 23 didn't see it in the scrapings because, obviously, 24 it had been degraded by oxidation. But then he 25 says the 1718 -- and I see this in my own work,</p>	<p>1 peaks. 2 Q. You remember Clavé couldn't confirm 3 degradation by FTIR? Do you remember that? 4 A. Well, that's what he said, but I believe 5 it's -- 6 Q. Do you think he's wrong? 7 A. I'm not saying that he's wrong. I'm 8 saying that he -- he wrote that. That's what he 9 wrote in his paper, but I -- I believe that that's 10 absorbing in the -- in the -- I need to find the 11 number. That's absorbing in that same range. Let 12 me just find the number. 13 Q. Let's go -- I'll mark that as -- where are 14 we? 13? 15 A. But I -- just for the record, I have 16 testified about all this before, these papers. I 17 have. 18 Q. You brought it up. You said Clavé made 19 some finding about oxidative degradation by FTIR. 20 And if you look at page 267 of the study, it says, 21 "Direct oxidation of the polypropylene, the FTIR 22 analysis neither confirmed nor excluded oxidation 23 of polypropylene in the in vivo environment." 24 Correct? 25 A. That's what he wrote.</p>
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<p>1 this 1718 inverse centimeters is a carbonyl band 2 most likely associated with esters like my 3 materials can be associated with acids. The 1638 4 and the 1618, these are beta ketone esters, acids, 5 acrylics. It's just -- there's -- there's a 6 number of oxidized species that can absorb in that 7 range. That's -- that's what I'm saying. 8 Q. Okay. The Wood article is the only source 9 that I found in the information that you provided 10 to me that is suggestive of where one would expect 11 to find a carbonyl peak for oxidative degradation. 12 Are you aware of any other studies? 13 A. Well, there's the Ethicon studies, the 14 Ethicon -- -- 15 Q. I'm not talking -- 16 A. -- documents. 17 Q. -- about Ethicon papers now. I'm talking 18 about peer reviewed publications on which you 19 rely. 20 MR. BOWMAN: Object to form. 21 THE WITNESS: There's Clavé. Clavé 22 did FTIR. 23 BY MR. THOMAS: 24 Q. Okay. 25 A. I need to look and see where he was seeing</p>	<p>1 Q. Okay. 2 A. But, again, I mean, I -- I've been asked 3 questions about these papers many times. 4 Q. Okay. I'm not going to -- and I didn't 5 intend to ask you about it until you brought it 6 up. 7 A. Well, you brought it up. You were asking 8 about FTIR. 9 Q. Okay. When you and Dr. Dunn did your 10 testing that we talked about in Exhibit No. 12, 11 did you discuss conducting any molecular weight 12 tests? 13 A. We did, and there -- there just wasn't 14 enough sample. 15 Q. Okay. Did you discuss doing any other 16 analytical chemistry tests on the samples? 17 A. I don't remember. The FTIR, the XPS, and 18 the SEM seem to be the -- the best we could do 19 with the materials that we had. 20 Q. Okay. Did you and Dr. Jordi -- excuse me. 21 Did you and Dr. Dunn ever discuss doing 22 analytical chemistry testing on actual Ethicon 23 mesh explants? 24 A. I think that we -- I -- I don't know if we 25 actually did for Ethicon. I can't remember.</p>

23 (Pages 86 to 89)

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<p style="text-align: right;">Page 90</p> <p>1 Q. You did for other manufacturers. We</p> <p>2 talked about them before. I'm not going to plow</p> <p>3 that ground again.</p> <p>4 A. We did do for -- there was another report</p> <p>5 where we did that, but I don't -- I can't remember</p> <p>6 specifically if we had a discussion about doing</p> <p>7 that for an explant for an Ethicon case. I can't</p> <p>8 remember.</p> <p>9 Q. Do you know Howard Jordi?</p> <p>10 A. Yes.</p> <p>11 Q. Have you met Dr. Jordi?</p> <p>12 A. I've not met him. I know who he is.</p> <p>13 Q. Have you read his reports?</p> <p>14 A. It's been a while.</p> <p>15 Q. Have you read his expert witnesses reports</p> <p>16 that he submitted against Ethicon?</p> <p>17 A. I believe so, but not recently.</p> <p>18 Q. Okay. And you're aware of the molecular</p> <p>19 weight testing that he conducted on the Ethicon</p> <p>20 meshes?</p> <p>21 A. I don't remember his molecular weight</p> <p>22 testing.</p> <p>23 Q. What -- what testing do you remember that</p> <p>24 he conducted?</p> <p>25 A. I thought he did some pathology similar to</p>	<p style="text-align: right;">Page 92</p> <p>1 BY MR. THOMAS:</p> <p>2 Q. Let's go back to Exhibit No. 9, please.</p> <p>3 Dr. Guelcher, in Exhibit No. 9 we talked a minute</p> <p>4 ago about the oxidative media in which you placed</p> <p>5 these TVT meshes for a period of up to six weeks.</p> <p>6 A. Mm-hmm.</p> <p>7 Q. What would happen if this oxidative media</p> <p>8 in that form was placed in the body?</p> <p>9 MR. BOWMAN: Object to form.</p> <p>10 THE WITNESS: What do you mean if it</p> <p>11 were placed in the body?</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. If -- if you cut somebody open in the</p> <p>14 pelvic floor and placed this oxidative media in</p> <p>15 the pelvic floor, what would it do to tissue in</p> <p>16 the body?</p> <p>17 MR. BOWMAN: Object to form.</p> <p>18 THE WITNESS: Why would you do that?</p> <p>19 This -- that's not what it's intended to do. It's</p> <p>20 intended to simulate the privileged</p> <p>21 microenvironment between the adherent macrophage</p> <p>22 and the biomaterial surface. So it doesn't -- you</p> <p>23 would never -- it's a -- it's a -- to just pour it</p> <p>24 in the pelvic floor, I don't -- I don't get it.</p> <p>25</p>
<p style="text-align: right;">Page 91</p> <p>1 what Dr. Iakovlev did, but I don't -- I don't</p> <p>2 remember the details of what -- I know he talked</p> <p>3 about oxidation, but I just can't remember the</p> <p>4 details of what he did.</p> <p>5 Q. Do you know he's an expert witness in this</p> <p>6 case?</p> <p>7 A. I didn't know that, but...</p> <p>8 Q. Did you know he submitted a report in this</p> <p>9 case?</p> <p>10 A. If he had, I don't remember looking at it.</p> <p>11 Q. Do you know the extent to which findings</p> <p>12 that he makes in the work that he's done on</p> <p>13 Ethicon mesh are consistent or inconsistent with</p> <p>14 your work?</p> <p>15 MR. BOWMAN: Object to form.</p> <p>16 THE WITNESS: I don't know.</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Do you know the extent to which the</p> <p>19 findings that he made in his work in this</p> <p>20 litigation are consistent or inconsistent with the</p> <p>21 work of Dr. Iakovlev?</p> <p>22 MR. BOWMAN: Object to form.</p> <p>23 THE WITNESS: I don't know that</p> <p>24 either.</p> <p>25</p>	<p style="text-align: right;">Page 93</p> <p>1 BY MR. THOMAS:</p> <p>2 Q. Well, whether you get it or not, do you</p> <p>3 have a -- do you have any idea about what would</p> <p>4 happen if you introduced this oxidative solution</p> <p>5 into the tissue in the pelvic floor?</p> <p>6 MR. BOWMAN: Object to form.</p> <p>7 THE WITNESS: It would oxidize</p> <p>8 tissue.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. It would kill tissue?</p> <p>11 A. That's what -- I mean...</p> <p>12 Q. Yes?</p> <p>13 A. I mean, it would react. I don't</p> <p>14 know what -- I don't want to use the word kill</p> <p>15 tissue, but it -- there would be a reaction with</p> <p>16 the tissue.</p> <p>17 Q. And what kind of reaction would take</p> <p>18 place?</p> <p>19 A. An oxidative reaction.</p> <p>20 Q. And what would that do to the tissue?</p> <p>21 A. I don't know. I've never done it. I</p> <p>22 don't -- I don't know why anybody would do that.</p> <p>23 That's not what this medium is intended to do.</p> <p>24 Q. Well, it is trying to replicate the in</p> <p>25 vivo conditions, correct?</p>

24 (Pages 90 to 93)

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<p>1 A. No, that's not what I said. I said it's 2 replicating the privileged microenvironment 3 between an adherent macrophage and a surface that 4 it's attached to. That's what's in my report. 5 Q. So just so I'm clear, this oxidative... 6 A. Well, that's what it says here: 7 "Simulates the microenvironment between an 8 adherent macrophage and the biomaterial surface." 9 Q. So -- 10 A. So it's contained at a very specific 11 location. It's not just dumped all over the body. 12 Q. Okay. So it does not replicate what 13 happens when mesh is placed in the body; is that 14 fair? 15 A. No, that's not fair at all. 16 MR. BOWMAN: Object to form. 17 THE WITNESS: I've already answered 18 the question. It replicates -- when mesh is 19 placed in the body, the surface is populated by 20 adherent macrophages, and there's a privileged 21 microenvironment between that macrophage and that 22 polymer surface, and that area is exposed to a -- 23 a medium like this. That's what this is -- this 24 is what Dr. Anderson showed in the '90s, is that 25 he could reproduce in vivo oxidation by using</p>	<p>1 biomaterial surface before the macrophages get 2 there, don't they? 3 MR. BOWMAN: Object to form. 4 THE WITNESS: Well, they -- they 5 mediate cell attachments, so the proteins adsorb 6 first and then the cells can attach. 7 BY MR. THOMAS: 8 Q. Okay. And is the adsorption a chemical 9 reaction? 10 A. Well, adsorption can be physical or 11 chemical. It can be a -- physisorption would be a 12 weak bonding, like van der Waals forces, ionic 13 interactions. That could be a reversible, we 14 call, physisorption. Chemisorption is when it 15 adsorbs and there's a chemical reaction. So it 16 could be either one. 17 Q. Have you studied the extent to which 18 proteins adsorb onto TVT PROLENE mesh upon 19 implantation in the body? 20 A. Have I studied that? What do you mean by 21 that? 22 Q. Just that. Have you looked at that issue? 23 A. Have I looked at it? 24 Q. Yes. 25 A. Well, I mean, there are -- it's a</p>
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<p>1 accelerated in vitro test in this medium. I don't 2 know how else to say it. 3 BY MR. THOMAS: 4 Q. Okay. But you agree it's a bad idea to 5 introduce this oxidative media into the body just 6 by itself? 7 MR. BOWMAN: Object to form. 8 THE WITNESS: There's no reason to do 9 it. 10 MR. THOMAS: Okay. 11 THE WITNESS: That's not the purpose 12 of the test. 13 BY MR. THOMAS: 14 Q. Doctor, do you know what protein 15 adsorption is? 16 A. Yes. 17 Q. What is protein adsorption? 18 A. Well, proteins adsorb to a surface. 19 MR. THOMAS: That's A-D, adsorb, as 20 opposed to absorb. 21 THE WITNESS: Proteins adsorb to a 22 surface. If you implant a biomaterial, there's 23 proteins that adsorb to the surface. 24 BY MR. THOMAS: 25 Q. And those proteins adsorb to the</p>	<p>1 well-known fact that protein adsorbs to many 2 polymers. 3 Q. And you would expect -- 4 A. So it's in the Ethicon documents. It's in 5 the papers. I've published papers with protein 6 adsorption data. It's -- it's a well-known 7 phenomenon. 8 Q. And you would expect upon implantation for 9 proteins to adsorb and bind to the PROLENE 10 polypropylene, correct? 11 A. Yeah. They would adsorb to the surface. 12 Q. And create a bond with the surface that 13 varies in strength depending on the circumstances 14 of the adsorption, correct? 15 A. That's reasonable. 16 Q. And that that bond will keep those 17 proteins on the polypropylene until they're 18 removed? 19 MR. BOWMAN: Object to form. 20 THE WITNESS: I mean, it's reverse -- 21 if it's reversible adsorption, there's an 22 equilibrium. So the amount of protein in 23 concentration in the liquid is going to have an 24 effect on the amount of protein that's adsorbed on 25 the surface if it's a physisorption. And, you</p>

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<p style="text-align: right;">Page 98</p> <p>1 know, they would -- when you remove the tissue, 2 you're most likely removing these proteins, and 3 this is -- this is what Dr. Iakovlev was doing, 4 removing the tissue. 5 BY MR. THOMAS: 6 Q. Dr. Iakovlev -- 7 A. I don't know what you're asking. 8 Q. Dr. Iakovlev doesn't remove any tissue 9 when he does his tissue samples, does he? 10 A. I was referring to the -- to the XPS 11 measurements that we did. He manually dissected 12 them so we could do the XPS. That's what I was -- 13 the context of what I was saying. 14 Q. Okay. But until these adsorbed proteins 15 are removed from the polypropylene, they're bound 16 to the polypropylene, aren't they? 17 A. Yes. And you can remove them. There was 18 some work done at Ethicon removing them with 19 solvents. And the conclusions in those documents 20 is there's a mix of protein and oxidized 21 polypropylene on the surface. This idea that 22 the -- and that the -- that the polymer is 23 degrading, oxidizing, it becomes porous, and then 24 proteins can get trapped in there. And so the 25 conclusions from a lot of Mr. Burkley's studies is</p>	<p style="text-align: right;">Page 100</p> <p>1 that's what I said in December. I don't know. 2 Q. Okay. Doctor, you -- do you have an 3 opinion that the Ethicon TVT should be 4 significantly changed or modified in its design? 5 MR. BOWMAN: Object to form. 6 THE WITNESS: I believe that the TVT 7 is a heavyweight mesh. We know that the foreign 8 body reaction associated with heavyweight mesh can 9 be more severe. And so, you know, it's going -- 10 all these -- the more polypropylene that's there, 11 the more foreign body reaction, oxidation, 12 degradation, is going to be present. 13 BY MR. THOMAS: 14 Q. Are you of the opinion that there should 15 be a different material used? 16 A. I've never expressed an opinion about 17 different materials to be used for mesh. 18 Q. Okay. Do you have -- strike that. 19 Are you prepared to offer an opinion at 20 all in this case that the Ethicon device needs to 21 be changed or modified in its design? 22 MR. BOWMAN: Object to form. Can we 23 just get specific to the device you're talking 24 about? 25 THE WITNESS: Yeah.</p>
<p style="text-align: right;">Page 99</p> <p>1 it's a mixed of protein and oxidized 2 polypropylene. 3 MR. THOMAS: Move to strike 4 everything after "yes." 5 THE WITNESS: Why? 6 MR. THOMAS: Because the rest of it's 7 not responsive. 8 MR. BOWMAN: And just FYI, he's 9 asking you questions, you're not allowed to ask 10 him -- 11 THE WITNESS: Okay. I'm sorry. I 12 thought we were talking about protein adsorption. 13 MR. BOWMAN: I have to amend my 14 stipulation earlier. PCT-168 actually refers to 15 Dr. Dunn's file on Boston Scientific, not Ethicon. 16 I apologize for that. 17 BY MR. THOMAS: 18 Q. Okay. I have to ask the question then. 19 Is PCT-168 testing Ethicon meshes or Boston 20 Scientific meshes? 21 A. I don't know. That's Dr. Dunn's numbering 22 system. I don't -- I don't know what -- 23 Q. They call it TVT. 24 A. I mean, if you really want to know, you 25 should depose Dr. Dunn about it. I don't --</p>	<p style="text-align: right;">Page 101</p> <p>1 MR. THOMAS: The Ethicon TVT device. 2 THE WITNESS: Could you repeat the 3 question? 4 BY MR. THOMAS: 5 Q. Dr. Guelcher, do you have the opinion that 6 Ethicon should change or modify the TVT device, 7 and if so, how? 8 A. Well, I -- I thought I just answered that. 9 It's a -- it's a heavyweight mesh. Ethicon's own 10 documents even point to the fact that a 11 lighter-weight mesh would elicit a less intense 12 inflammatory response, oxidation, degradation, 13 less mesh is better. This is a concept that I've 14 testified about previously. It's in the 15 documents. 16 Q. Okay. Do you have an opinion as to how 17 that change in design should be made? 18 A. I don't believe that opinion was expressed 19 in my report other than just to say a 20 lighter-weight mesh would -- less mesh is better. 21 I mean, there's a -- but I didn't really talk 22 about that. I mean, I would say that a 23 lighter-weight mesh would be expected to invoke 24 less inflammation, less foreign body reaction, 25 less oxidation, less degradation.</p>

26 (Pages 98 to 101)

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<p>1 Q. Do you have an opinion that any mesh 2 product could be reasonably safe and effective for 3 its intended use in the pelvic floor? 4 MR. BOWMAN: Object to form. 5 THE WITNESS: I think I've testified 6 to, and it's in the report, that the pelvic floor 7 is very different from the abdominal wall. These 8 meshes behave differently in the pelvic floor than 9 they do in the abdominal wall, and -- and more 10 testing needs to be done to evaluate their safety 11 in the pelvic floor. 12 BY MR. THOMAS: 13 Q. So is it fair to understand that you do 14 not have an opinion that any mesh product could be 15 reasonably safe and effective for its intended use 16 in the pelvic floor? You don't have that opinion 17 today? 18 A. Not without further testing. 19 I -- I should clarify my answer. I don't 20 believe it would be safe unless it were tested to 21 make sure that it was safe because of the problems 22 with polypropylene oxidation, degradation. 23 Q. Is it fair to understand that whatever 24 design modifications are made in order to reduce 25 the risks as you've identified them in your</p>	<p>1 A. Yeah. 2 Q. And you'd also expect this change in 3 design to be subject to review by the FDA; is that 4 fair? 5 A. I'm not -- I can't speak about what -- I'm 6 not really -- it's not in my report about what FDA 7 should and should not do. I mean, I understand 8 that FDA reviews biomedical device applications. 9 I understand that. But I'm not -- I don't want to 10 speculate about what FDA would do or would not do. 11 Q. You would expect FDA, though, to look at 12 any change in design? 13 A. It would have to be submitted as a -- as 14 a -- either a 510(k) or a PMA that would be 15 reviewed by FDA. 16 Q. Okay. So the FDA could make whatever 17 determinations they needed to make in the change 18 of the design and the safety and efficacy of the 19 product, fair? 20 A. Say that again. I didn't quite catch what 21 you meant. 22 MR. THOMAS: I need your help. 23 (Reporter read back requested 24 material.) 25 THE WITNESS: Well, FDA would not</p>
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<p>1 report, that design modification will have to be 2 tested before it will be used in humans? 3 A. What I testified in Perry is I would have 4 liked to have seen more testing done in in vitro 5 oxidative medium in large animals. This could be 6 done in the sheep models. You could do -- compare 7 abdominal wall to the pelvic floor. There could 8 be more preclinical testing that would be done. 9 That's what's in the report. 10 Q. I'm not really after what you've testified 11 before. 12 A. Okay. 13 Q. This is really a different question. 14 You've told me ways in which you think Ethicon 15 should change the design of its product. You've 16 also told me that you think there should be 17 testing done on any change in the design of the 18 product before it would be introduced into use; is 19 that fair? 20 A. That's fair. 21 Q. Okay. And the testing that you describe 22 would be both clinical, preclinical, in vitro, a 23 variety of tests to make sure that this change of 24 design would be safer than the existing TVT 25 design, fair?</p>	<p>1 change the design. They would ask the company, 2 say, for more information, but they wouldn't -- I 3 don't think that FDA designs products. 4 BY MR. THOMAS: 5 Q. But they would review the design in the 6 context of the safety and efficacy for the 7 patients it was intended to treat, fair? 8 A. They would review those data, yeah. 9 Q. Okay. 10 MR. THOMAS: I need to take a break 11 again. Excuse me. 12 (Luncheon recess observed.) 13 BY MR. THOMAS: 14 Q. Doctor, the testing that's done in 15 Exhibit 12 is -- is good, sound, reliable testing, 16 isn't it? 17 A. Yes, I believe so. 18 Q. And the conclusions that you've -- strike 19 that. 20 The results that are contained in Exhibit 21 12 you believe to be scientifically valid results? 22 A. Yes. 23 Q. And the comments that you made to the 24 International Urogynecological Association about 25 those findings were fair and accurate at the time</p>

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<p>1 that you gave them, weren't they?</p> <p>2 A. I believe so.</p> <p>3 Q. Why aren't you relying on this testing for</p> <p>4 your report?</p> <p>5 MR. BOWMAN: Objection to form.</p> <p>6 THE WITNESS: We haven't published it</p> <p>7 yet.</p> <p>8 BY MR. THOMAS:</p> <p>9 Q. Okay. Is that the sole reason?</p> <p>10 A. Probably the main reason.</p> <p>11 Q. Do you plan to publish these -- this data?</p> <p>12 A. We're discussing it.</p> <p>13 Q. Have you prepared a manuscript?</p> <p>14 A. It's in draft form, but we're -- we're</p> <p>15 deciding what to do.</p> <p>16 Q. Has it been submitted to any journals?</p> <p>17 A. We submitted it to the IUGA, the</p> <p>18 International -- since we had a podium</p> <p>19 presentation, we submitted it to the -- the</p> <p>20 International Urogynecology Journal.</p> <p>21 Q. Okay. And are they considering it or did</p> <p>22 they refuse it?</p> <p>23 A. They didn't want to publish it. We didn't</p> <p>24 have -- yeah, they didn't want to publish it.</p> <p>25 Q. Why not?</p>	<p>1 believed that I should be a co-author on the</p> <p>2 paper. But I -- I did -- yeah, it's...</p> <p>3 Q. Did you have any involvement in the peer</p> <p>4 review process for the paper?</p> <p>5 A. Dr. Iakovlev handled all of that as a</p> <p>6 corresponding author.</p> <p>7 Q. Do you have -- maintain a file about the</p> <p>8 submission of this paper to different journals?</p> <p>9 A. I don't know what I've got on that.</p> <p>10 Q. Was this paper submitted to multiple</p> <p>11 journals?</p> <p>12 A. I believe -- I believe it was submitted to</p> <p>13 other journals.</p> <p>14 Q. Do you know which ones they were submitted</p> <p>15 to?</p> <p>16 A. No, I don't remember right now.</p> <p>17 Q. Were there comments made on the journal</p> <p>18 submission?</p> <p>19 MR. BOWMAN: Object to form.</p> <p>20 THE WITNESS: Well, we -- I mean,</p> <p>21 I'm -- there were -- I don't remember what --</p> <p>22 exactly what happened with those other reviews.</p> <p>23 That was a while ago.</p> <p>24 BY MR. THOMAS:</p> <p>25 Q. Do you maintain a file of the comments</p>
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<p>1 A. We didn't have much clinical data.</p> <p>2 Q. Have you submitted it to any other</p> <p>3 journals?</p> <p>4 A. No.</p> <p>5 Q. Is there a manuscript form that you</p> <p>6 submitted to the International Urogynecological</p> <p>7 Association?</p> <p>8 A. There's a PDF that we uploaded to the --</p> <p>9 the submitted manuscript.</p> <p>10 Q. Do you have a file of information that you</p> <p>11 maintain concerning your submission of this data</p> <p>12 to the IUGA journal?</p> <p>13 A. I have documents related to that, I</p> <p>14 believe.</p> <p>15 Q. Okay. Now, for Exhibit No. 10, which is</p> <p>16 the paper that you co-authored with Dr. Iakovlev</p> <p>17 and Dr. Bendavid, I believe you said your</p> <p>18 responsibility there was limited to the</p> <p>19 myeloperoxidase; is that fair?</p> <p>20 A. I didn't say it was limited to it. I said</p> <p>21 that -- I believe what I said was that my primary</p> <p>22 contribution, it was my -- I suggested that we</p> <p>23 stain for myeloperoxidase, and Dr. Iakovlev</p> <p>24 stained for myeloperoxidase. We saw positive</p> <p>25 staining. And based on that contribution, he</p>	<p>1 that you received on the -- what you submitted to</p> <p>2 the journals?</p> <p>3 A. I don't know. I don't...</p> <p>4 Q. Did -- did you share your draft of</p> <p>5 Exhibit 9 with plaintiff's counsel before it was</p> <p>6 published in the International Urogynecological</p> <p>7 Journal?</p> <p>8 A. Well, I submitted it. I wrote a -- I</p> <p>9 wrote the abstract and I submitted -- I don't</p> <p>10 remember sending it to plaintiff's counsel before</p> <p>11 I submitted it. I can't remember, but I don't</p> <p>12 think I did.</p> <p>13 Q. Did you discuss your plans to submit this</p> <p>14 abstract to the International Urogynecological</p> <p>15 Association with plaintiff's counsel before you</p> <p>16 did so?</p> <p>17 A. I don't remember. I decided to do it</p> <p>18 maybe -- when the workshop came up, I think, is</p> <p>19 when I decided to submit the abstract. It's not a</p> <p>20 meeting that I'd normally go to, so I just -- I</p> <p>21 don't remember the timing of everything.</p> <p>22 Q. Okay. But at the same time that you were</p> <p>23 having the meeting with plaintiff's counsel to</p> <p>24 plan for the workshop is the same time that you</p> <p>25 planned to submit this abstract; is that fair?</p>

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<p>1 A. No, I don't believe so because the</p> <p>2 workshop was -- the workshop was probably -- it</p> <p>3 was a proposal to include in a meeting. By the</p> <p>4 time I submitted that abstract, the sessions had</p> <p>5 already been determined.</p> <p>6 Q. Okay. So you had already signed --</p> <p>7 A. The workshop was first, I think.</p> <p>8 Q. Okay.</p> <p>9 A. That's typical.</p> <p>10 Q. All right. Exhibit No. 10, the article</p> <p>11 that you co-authored with Dr. Iakovlev and</p> <p>12 Dr. Bendavid?</p> <p>13 A. Yes.</p> <p>14 Q. Did -- do you know whether this article</p> <p>15 was reviewed by plaintiff's counsel before it was</p> <p>16 submitted?</p> <p>17 A. I don't know who -- like I said,</p> <p>18 Dr. Iakovlev is the corresponding author. I</p> <p>19 don't -- I -- I don't know what he did there.</p> <p>20 Q. On page -- on -- go back to Exhibit No. 9</p> <p>21 real quick. On page 2 under "Disclosure Block,"</p> <p>22 did you decide what to include under the</p> <p>23 disclosure block?</p> <p>24 A. I'm looking for it.</p> <p>25 No. Well, okay. I need to explain that.</p>	<p>1 A. I don't remember. That's -- I -- I don't</p> <p>2 know that it was that detailed.</p> <p>3 Q. At the time of this publication and for</p> <p>4 years prior to that time, Dr. Dunn had also been a</p> <p>5 consultant who would testify as an expert, hasn't</p> <p>6 he?</p> <p>7 A. That's right.</p> <p>8 Q. Do you know why he didn't disclose</p> <p>9 anything?</p> <p>10 A. That's an error. And I don't -- when I</p> <p>11 presented this talk, I had a disclosure slide. I</p> <p>12 don't know why it says nothing to disclose. It</p> <p>13 may have been that he had to fill that out and</p> <p>14 didn't realize it. I don't -- I don't know.</p> <p>15 That's an error. But I did clarify that point --</p> <p>16 Q. Is the --</p> <p>17 A. -- in the talk.</p> <p>18 Q. I'm sorry.</p> <p>19 A. Yeah.</p> <p>20 Q. Is the disclosure slide one of the ones</p> <p>21 that you produced to me?</p> <p>22 A. Well, it's -- it's in the -- it's -- you</p> <p>23 have slides for the AIChE presentation and for the</p> <p>24 IUGA presentation, and I believe there's a</p> <p>25 disclosure slide that says we were testifying</p>
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<p>1 I -- I'm going by my memory, but these are -- all</p> <p>2 the meetings have different requirements. I think</p> <p>3 that this one may have had specific blocks that I</p> <p>4 could choose from. That's probably why -- I --</p> <p>5 that says "consulted" and "consulting fee."</p> <p>6 Those -- those look like fields that I had to</p> <p>7 select, is what I -- but I don't remember what I</p> <p>8 did exactly.</p> <p>9 Q. What did you intend to convey when you</p> <p>10 said you were a consultant?</p> <p>11 A. Well, I think consultant is probably what</p> <p>12 I had to select to choose expert witness.</p> <p>13 Q. Was there --</p> <p>14 A. I --</p> <p>15 Q. I'm sorry.</p> <p>16 A. I'm sorry. I don't think that I chose --</p> <p>17 I can't remember, but I -- this -- that doesn't</p> <p>18 look like words that I would use to describe my</p> <p>19 activities, which probably tells me that there was</p> <p>20 a field that I had to fill out, and that was the</p> <p>21 closest. That's -- that's my best guess, but I</p> <p>22 don't -- I don't really remember.</p> <p>23 Q. Was there an opportunity to disclose that</p> <p>24 you were a testifying expert for the plaintiffs in</p> <p>25 the mesh litigation?</p>	<p>1 in -- in -- in the litigation.</p> <p>2 Q. Okay. Whatever slides you used in your</p> <p>3 presentation have been produced to me today?</p> <p>4 A. Yeah, I believe so. I -- I produced</p> <p>5 those.</p> <p>6 Q. Doctor, I've tried mightily not to</p> <p>7 reinvent the wheel and go through the opinions</p> <p>8 that you've given in previous depositions. Have</p> <p>9 we covered all of the opinions that you're</p> <p>10 prepared to give in this case?</p> <p>11 A. Let me look at them one more time to be</p> <p>12 sure. I want to be accurate.</p> <p>13 I believe so.</p> <p>14 Q. Okay. The only question I have is on</p> <p>15 page 17 of your report.</p> <p>16 A. Okay.</p> <p>17 Q. You talk about the failure modes and</p> <p>18 effects analysis.</p> <p>19 A. Yes.</p> <p>20 Q. That's the first time I've seen that in</p> <p>21 any of your reports. Is that new? Dr. Dunn</p> <p>22 testified about it in the Huskey case.</p> <p>23 A. He was -- he was deposed on -- I don't</p> <p>24 believe he --</p> <p>25 Q. He gave a deposition --</p>

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<p>1 A. Yes.</p> <p>2 Q. -- in that case. That's what I meant.</p> <p>3 I'm sorry.</p> <p>4 A. Oh, that's what you -- okay. I</p> <p>5 understand. Yeah. I think that may have been the</p> <p>6 first -- I can't remember if that's the first time</p> <p>7 I wrote that or not, if it's in another report.</p> <p>8 Q. You cite no documents in connection with</p> <p>9 that opinion. Are you prepared to offer that</p> <p>10 opinion at trial?</p> <p>11 MR. BOWMAN: Object to form.</p> <p>12 THE WITNESS: I -- I don't intend to</p> <p>13 speak about failure modes and effects analysis at</p> <p>14 trial.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. Okay. So is it fair for me to be able to</p> <p>17 eliminate from your opinion the paragraph</p> <p>18 beginning "finally" to the end?</p> <p>19 A. Not -- just that sentence that addresses</p> <p>20 FMEA --</p> <p>21 Q. Okay.</p> <p>22 A. -- is -- is not something that I would</p> <p>23 testify about at trial.</p> <p>24 I would not testify about FMEA.</p> <p>25 Q. Very good.</p>	<p>1 EXAMINATION</p> <p>2 BY MR. BOWMAN:</p> <p>3 Q. So, Dr. Guelcher, you've looked at</p> <p>4 Exhibit 12, the folder for PCT-168?</p> <p>5 A. Yes.</p> <p>6 Q. And you've already testified that you</p> <p>7 hadn't reviewed this prior to today?</p> <p>8 A. That's right.</p> <p>9 Q. You also testified that you're not relying</p> <p>10 on anything in this document for the opinions that</p> <p>11 you're expressing at trial; is that right?</p> <p>12 A. Yes, that's correct.</p> <p>13 Q. Can I ask you, do you know what Ethicon</p> <p>14 product was examined for this report?</p> <p>15 A. I believe it was a TVT laser-cut mesh.</p> <p>16 Q. And is it your understanding that your</p> <p>17 reports being offered in this case are -- are --</p> <p>18 do they -- do they at all apply to the laser-cut</p> <p>19 mesh?</p> <p>20 A. No. My understanding, it's machine cut.</p> <p>21 Q. Have you at any time ever held in your</p> <p>22 hand, examined, or looked at a -- to your</p> <p>23 knowledge, a -- a mechanical-cut TVT?</p> <p>24 A. Not to my knowledge.</p> <p>25 Q. Do you know, is -- besides the fact that</p>
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<p>1 And I think everything else is stuff</p> <p>2 that's been covered in prior depositions. Is that</p> <p>3 to the best of your knowledge?</p> <p>4 A. To the best of my knowledge, yes.</p> <p>5 MR. THOMAS: I'm going to stop. I'm</p> <p>6 going to hold the deposition open pending some</p> <p>7 issues, but we may or may not -- I may or may not</p> <p>8 seek to return. But those are all the questions I</p> <p>9 have right now.</p> <p>10 MR. BOWMAN: Can -- do you mind --</p> <p>11 what the issues are? Can you tell me what they</p> <p>12 are?</p> <p>13 MR. THOMAS: Questions about those</p> <p>14 documents, the test results that he's not able to</p> <p>15 talk about without review. And I -- I probably</p> <p>16 won't come back, but I -- I just don't know until</p> <p>17 I think about it. And you may have a rebuttal</p> <p>18 report anyway that may solve all that problem</p> <p>19 depending on what you see today.</p> <p>20 MR. BOWMAN: You know, I have very</p> <p>21 little, I think, in -- in terms of redirect. I</p> <p>22 think I'll just go now, if that's all right.</p> <p>23 MR. THOMAS: That's fine.</p> <p>24 MR. BOWMAN: Okay.</p> <p>25</p>	<p>1 Dr. Dunn took the FTIR and that Dr. Rogers</p> <p>2 compiled the data for the XPS test, and besides</p> <p>3 what you've already testified about the protocol</p> <p>4 for the solution used for this testing, is there</p> <p>5 anything else that you can tell us in regards to</p> <p>6 Exhibit 12?</p> <p>7 A. Not at this time, no.</p> <p>8 Q. Doctor, in your report, did you ever, and</p> <p>9 have you -- and are you offering any opinion as to</p> <p>10 a specific material or design of the product that</p> <p>11 could be used instead of what you understand to be</p> <p>12 the design of the mechanical-cut TVT?</p> <p>13 A. No, I'm not referring to a specific</p> <p>14 design.</p> <p>15 MR. BOWMAN: I think that's all I</p> <p>16 have.</p> <p>17 MR. THOMAS: Thank you. That's all I</p> <p>18 have.</p> <p>19 We have a couple of things we need to</p> <p>20 do. We're going to take Exhibit 8, which is the</p> <p>21 thumb drive. We need to figure out a way to get a</p> <p>22 copy of this so that Dr. Guelcher doesn't lose his</p> <p>23 notebook.</p> <p>24 Last time we did that and got it back</p> <p>25 to you promptly. Are you comfortable with that?</p>

30 (Pages 114 to 117)

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<p>1 THE WITNESS: That's fine, as long as</p> <p>2 I can get it back.</p> <p>3 MR. HUTCHINSON: Before we go off the</p> <p>4 record, can we talk for just one second?</p> <p>5 MR. THOMAS: Hang on just a minute.</p> <p>6 (Brief recess observed.)</p> <p>7 MR. THOMAS: That's all. Thank you,</p> <p>8 Doctor.</p> <p>9 THE WITNESS: Okay.</p> <p>10 MR. THOMAS: Good to see you again.</p> <p>11 THE WITNESS: Thank you.</p> <p>12 MR. BOWMAN: Thank you.</p> <p>13 Do you wish to read and sign the</p> <p>14 transcript?</p> <p>15 THE WITNESS: I'll read.</p> <p>16 I'll look at it. Yes.</p> <p>17 MR. BOWMAN: Is that a 30-day window?</p> <p>18 MR. THOMAS: I believe so.</p> <p>19 THE WITNESS: Okay.</p> <p>20 MR. THOMAS: And I believe I have</p> <p>21 your address.</p> <p>22 MR. BOWMAN: And I think I just want</p> <p>23 to formally object to extending the deposition or</p> <p>24 holding it out, just -- just to get it out there.</p> <p>25 MR. THOMAS: That's fine. Thank you</p>	<p>1 REPORTER'S CERTIFICATE</p> <p>2</p> <p>3 I certify that the witness in the</p> <p>4 foregoing deposition, SCOTT GUELCHER, PH.D., was</p> <p>5 by me duly sworn to testify in the within entitled</p> <p>6 cause; that the said deposition was taken at the</p> <p>7 time and place therein named; that the testimony</p> <p>8 of said witness was reported by me, a Shorthand</p> <p>9 Reporter and Notary Public of the State of</p> <p>10 Tennessee authorized to administer oaths and</p> <p>11 affirmations, and said testimony, pages 1 through</p> <p>12 121 was thereafter transcribed to typewriting.</p> <p>13 I further certify that I am not of</p> <p>14 counsel or attorney for either or any of the</p> <p>15 parties to said deposition, nor in any way</p> <p>16 interested in the outcome of the cause named in</p> <p>17 said deposition.</p> <p>18 IN WITNESS WHEREOF, I have hereunto</p> <p>19 set my hand the 21st day of September 2015.</p> <p>20</p> <p>21</p> <p>22 _____</p> <p>23 GARY SCHNEIDER, RMR, CRR, TLCR No. 676</p> <p>24 My commission expires: 1/9/2018</p> <p>25</p>
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<p>1 all for your cooperation.</p> <p>2 MR. BOWMAN: All right. Thank you.</p> <p>3 (Proceedings adjourned at 12:32 P.M.)</p> <p>4 FURTHER DEPONENT SAITH NOT.</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 E R R A T A</p> <p>2</p> <p>3 I, SCOTT GUELCHER, PH.D., having read</p> <p>4 the foregoing deposition, Pages 1 through 121,</p> <p>5 taken September 15, 2015, do hereby certify said</p> <p>6 testimony is a true and accurate transcript, with</p> <p>7 the following changes, if any:</p> <p>8 PAGE LINE SHOULD HAVE BEEN REASON</p> <p>9 _____</p> <p>10 _____</p> <p>11 _____</p> <p>12 _____</p> <p>13 _____</p> <p>14 _____</p> <p>15 _____</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 _____</p> <p>25 _____</p> <p>26 _____</p> <p>27 _____</p> <p>28 _____</p> <p>29 _____</p> <p>30 _____</p> <p>31 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31 (Pages 118 to 121)

EXHIBIT K

Human plasma α_2 -macroglobulin promotes *in vitro* oxidative stress cracking of Pellethane 2363-80A: *In vivo* and *in vitro* correlations

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It is hypothesized in this study that the phenomenon of environmental stress cracking (ESC) in polyetherurethane is caused by a synergistic action of biological components in the body fluids, oxidative agents, and stress. An *in vitro* system is designed to mimic the *in vivo* system; human plasma contains certain biological components that can act as a stress cracking promoter, while H₂O₂ (Co) solution provides an oxidative reaction comparable to that observed in the respiratory burst of adherent macrophages and foreign-body giant cells. It is demonstrated that the phenomenon of *in vivo* stress cracking in

Pellethane 2363-80A is duplicated by an *in vitro* system that involves a pretreatment of prestressed specimens with human plasma at 37°C for 7 days followed by oxidation in 10% hydrogen peroxide with 0.10M cobalt chloride at 50°C for 10 days. The pretreatment with plasma has a synergistic effect with the oxidation by H₂O₂ (Co) treatment to produce ESC. A plasma component responsible for promoting stress cracking in Pellethane polyurethane is identified to be α_2 -macroglobulin (α_2 M). © 1993 John Wiley & Sons, Inc.

INTRODUCTION

With their unique and excellent physical, mechanical, and biocompatible properties, polyetherurethane elastomers have been used as constituent materials of many medical devices. Since these medical devices are often intended to perform reliably and safely while implanted in the body for prolonged periods of time, their long-term biostability is of vital importance to ensure safety and effectiveness when in contact with the tissue or body fluids of the living body. In certain limited circumstances, unintended biodegradation and surface cracking of polyurethanes have created increasing needs in biomaterials research to understand further the nature of biodegradation/biostability of the materials.^{1,2}

In vivo environmental stress cracking (ESC) in polyetherurethanes is believed to be a complex phenomenon. It is related to the chemical property of polyurethanes (e.g., polyether content),³⁻⁵ stress state of the material in use (e.g., design manufacturing processes),^{1,6} cell or tissue/polymer interactions (e.g.,

macrophage adhesion and foreign-body giant cell formation),⁷ and the body's physiological environment (i.e., so far unknown plasticizing or crack propagating agent).^{1,3,8} The mechanism for the ESC is still not clear due to unsuccessful duplication of this phenomenon by an *in vitro* method.^{3,6,8}

In this study, the investigation was conducted under a hypothesis that biological components in the body fluids, oxidative agents, and stress or strain act synergistically to produce the stress cracking of polyurethanes. An *in vitro* system that duplicates the ESC observed with polyetherurethane *in vivo* was

TABLE I
Biological Fluids Used for *In Vitro*
Treatment of Pellethane 2363-80A

Human blood plasma (citrate)
Plasma PEG fraction I
Plasma PEG fraction II
Plasma PEG fraction III
α_2 -Macroglobulin (2 mg/mL)
Ceruloplasmin (1 mg/mL)
Transferrin (2.3 mg/mL)
Lipoprotein (0.54 mg/mL)

*To whom correspondence should be addressed.

developed. Biological component(s) involved in ESC were identified. The relationships among biological components, stress state, and oxidation in PEU biodegradation are also discussed.

MATERIALS AND METHODS

Prestressed polyurethane specimens and different treatments

The poly(etherurethane) (PEU) elastomer used in this study was Pellethane 2363-80A. The base polymer was prepared from 4,4'-diphenyl bis(phenylisocyanate) (MDI) and poly(tetramethylene glycol) ($M_w = 1000$) (PTMEG) and chain extended with 1,4-butanediol. The polymer had a molecular weight of 95,000 relative to polystyrene. The bulk material contained two additives: a phenolic antioxidant and a bis(stearamide wax) processing agent.

The prestressed Pellethane 2363-80A tubing specimens (2 mm in diameter and 12.5 mm in length) were obtained from Medtronic, Inc. The polymer tubing was soaked in acetone for 1 h to extract the additives, prior to being stretched to 400% elongation over a mandrel. A detailed description of the specimen preparation is provided elsewhere.⁷ This type of prestressed specimen is known to undergo rapid biodegradation and stress cracking *in vivo* based on our previous study.⁷ For comparison, the 5- and 10-week implants in rats from the previous study were analyzed to correlate with the *in vitro* results in this study.

In the *in vitro* treatment, the prestressed specimens were immersed in the biological fluids at 37°C for 7 days, rinsed in distilled water, and put into an oxidizing solution at 50°C for 9 or 10 days. The oxidizing agent was an aqueous solution of 10% hydrogen peroxide (Fisher Scientific) and 0.10M cobalt chloride. The proposed role of cobalt chloride was to facilitate the decomposition of hydrogen peroxide to produce oxygen radical species.^{9,10} During the treatment, the peroxide/cobalt chloride solution was changed with fresh solution every 3 days. The biological fluids were human blood plasma, fractionated plasma, and simple protein solutions (Sigma), respectively (Table I). After the treatment, the polymer specimens were rinsed in distilled water, dried in air, and then stored in a vacuum desiccator for scanning electron microscopy (SEM, JOEL 840), ATR-FTIR, and GPC analyses.

The procedure for plasma fractionation with polyethylene glycol (PEG) was adapted from the method described by Hao et al.¹¹ All procedures were performed at 4°C. A beaker containing 100 mL citrated human plasma was placed in an ice bath. Solid PEG (M_w 4000, Polysciences, Inc.) was added slowly with stirring to plasma in the amount of 10 g/100 mL.

After 60 min, the 10% PEG precipitate, designated fraction I, was removed by centrifugation for 30 min at 2000 rpm. An additional 10 g of PEG was added to the supernatant followed by centrifugation to obtain fraction II (the 10–20% PEG precipitate) and fraction III (the supernatant containing 20% PEG). The precipitates were reconstituted to the original volume of plasma (100 mL) with phosphate-buffered saline (PBS). The distribution of proteins in the three fractions is shown in Table II.¹¹ Fraction I is rich in fibrinogen, plasminogen, C-3 component of complement, IgG, and β -lipoproteins. Fraction II is rich in α_2 -macroglobulin (α_2 -M), IgA, prothrombin, and other coagulation factors (prothrombin complex). Fraction III contains mainly albumin, α_1 -acid glycoprotein, transferrin, and 20% PEG.

ATR-FTIR and GPC analyses

To obtain ATR-IR spectra, the prestressed tubing specimens were opened by an incision along the tubing direction and the mandrels were removed. The ATR-IR spectra were obtained on the outer surface of the opened tubes with a Nicolet 800 spectrometer using the micro-ATR attachment made by Harrick Scientific, Inc., that featured two 4X beam condensers and continuous beam angle variation. To obtain degradation depth profiles, internal reflection elements (IRE) of Germanium with 60°, 45°, and 30° endface angles, and KRS-5 with 60° and 45° endface angles were used and combined with different incident angles of the IR beam.

The instrument employed for GPC analysis was a Varian DS-651 LC Star System with a 9010 Solvent Delivery System, a 9065 Polychrom UV diode-array detector, and a RI-4 refractive index detector set at 40°C. The running eluent was HPLC-grade THF with a flow rate of 1.0 mL/min. The standards and columns were obtained from Polymer Laboratories, Inc. (Amherst, MA). One set of calibration standards were used to calibrate a series of PL-Gel columns of 500, 10,000, and 100,000 Å pore size. Polystyrene calibration standards ranged from 1000 to 2,000,000 molecular weight, with a polydispersity (PDI) of 1.1. Reported molecular weight values were based on the two sets of calibration standards. Deconvolution of the GPC chromatograms was accomplished by using a spectral curve-fitting software (PeakFit 1.0, Jandel); two math functions, gaussian and exponentially modified gaussian, were employed.

Analysis of adsorbed plasma proteins

The adsorption and extraction of plasma proteins was performed on the original, unstrained Pellethane tubing (2 mm in diameter) material. Fifty milligrams

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TABLE II
Distribution of Selected Plasma Proteins in PEG Fractions (Ref. 11)

Plasma Proteins	Amount (mg/dL)	Fraction I wt% (mg/dL)	Fraction II wt% (mg/dL)	Fraction III wt% (mg/dL)
Albumin	3440	6 (206)	4 (138)	86 (2958)
IgG	740	88 (651)	15 (111)	1 (7)
Transferrin	223	6 (13)	22 (49)	58 (129)
α_2 -Macroglobulin	189	35 (66)	65 (123)	—
Fibrinogen	179	88 (158)	—	—
IgA	157	34 (53)	58 (91)	20 (31)
Haptoglobin	108	2 (2)	40 (43)	56 (61)
α -Lipoprotein	64	15 (10)	25 (16)	50 (32)
C-3 Component	56	93 (52)	7 (4)	—
α_1 -Acid glycoprotein	54	—	—	100 (54)
Ceruloplasmin	22	14 (3)	23 (5)	73 (16)
Plasminogen	16	69 (11)	19 (3)	—
β -Lipoprotein	16	100 (16)	—	—
Prothrombin	8	25 (2)	50 (4)	25 (2)
C-1 Esterase inhib.	4	—	—	100 (4)

of the polymer tubing was cut in half longitudinally to avoid entrapment of fluid while immersed in 10 mL of citrated plasma at 37°C for 7 days. After plasma treatment, the material was placed in a clean test tube and rinsed three times with PBS. The tubing material was then cut into small pieces that were transferred into a clean microtube. The adsorbed proteins were ex-

tracted in 0.25 mL of 1% sodium dodecyl sulfate (SDS) or the sample buffer used in SDS-Polyacrylamide Gel Electrophoresis (SDS-PAGE)¹² at room temperature for 24 h. Proteins in the extract were separated by SDS-PAGE using 7.5% or 4–15% acrylamide gradient gels. Separated proteins were visualized by silver stain (BioRad).

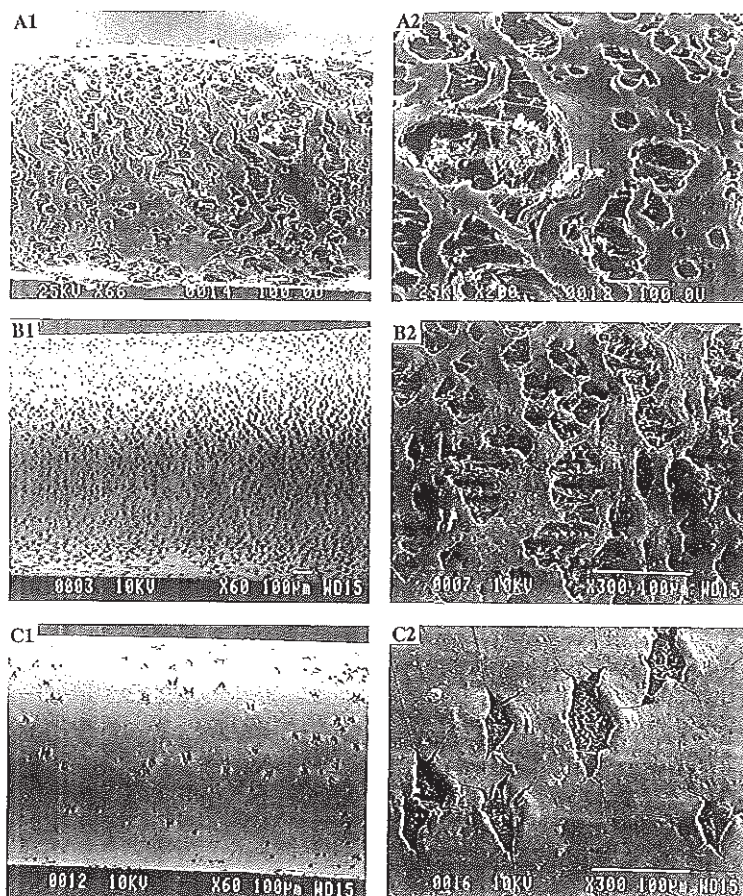


Figure 1. SEM pictures of prestressed specimens after treatments: (A1 and A2) 35 days (5 weeks) implanted; (B1 and B2) 7 day plasma plus 10-day peroxide/cobalt treated; (C1 and C2) 10-day peroxide/cobalt treated.

TABLE II
Distribution of Selected Plasma Proteins in PEG Fractions (Ref. 11)

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IgA	157	34 (53)	58 (91)	20 (31)
Haptoglobin	108	2 (2)	40 (43)	56 (61)
α -Lipoprotein	64	15 (10)	25 (16)	50 (32)
C-3 Component	56	93 (52)	7 (4)	—
α_1 -Acid glycoprotein	54	—	—	100 (54)
Ceruloplasmin	22	14 (3)	23 (5)	73 (16)
Plasminogen	16	69 (11)	19 (3)	—
β -Lipoprotein	16	100 (16)	—	—
Prothrombin	8	25 (2)	50 (4)	25 (2)
C-1 Esterase inhib.	4	—	—	100 (4)

of the polymer tubing was cut in half longitudinally to avoid entrapment of fluid while immersed in 10 mL of citrated plasma at 37°C for 7 days. After plasma treatment, the material was placed in a clean test tube and rinsed three times with PBS. The tubing material was then cut into small pieces that were transferred into a clean microtube. The adsorbed proteins were ex-

tracted in 0.25 mL of 1% sodium dodecyl sulfate (SDS) or the sample buffer used in SDS-Polyacrylamide Gel Electrophoresis (SDS-PAGE)¹² at room temperature for 24 h. Proteins in the extract were separated by SDS-PAGE using 7.5% or 4–15% acrylamide gradient gels. Separated proteins were visualized by silver stain (BioRad).

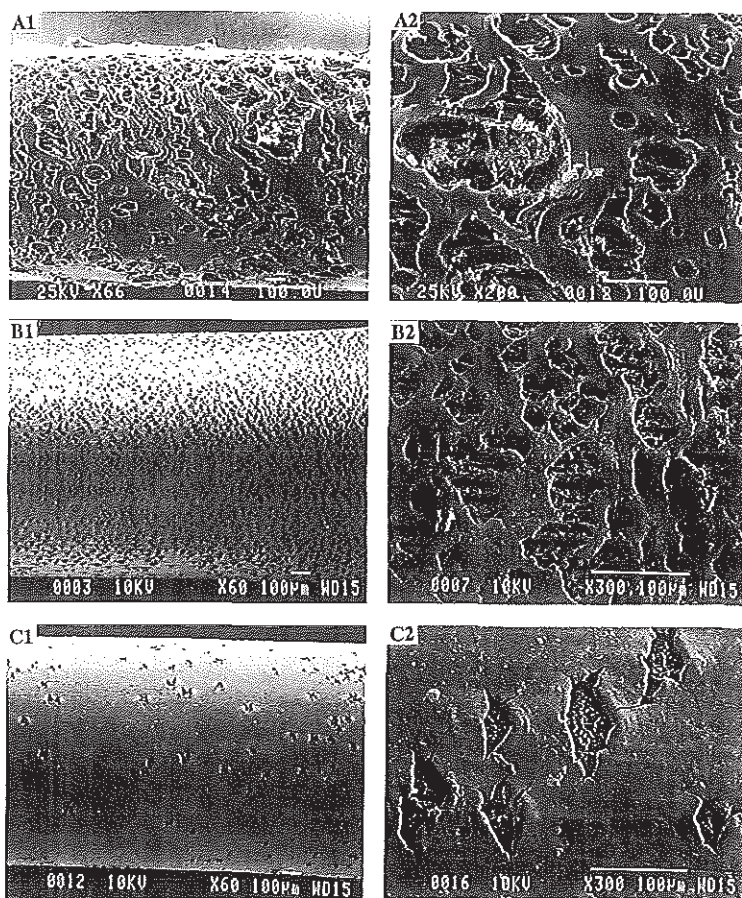


Figure 1. SEM pictures of prestressed specimens after treatments: (A1 and A2) 35 days (5 weeks) implanted; (B1 and B2) 7 day plasma plus 10-day peroxide/cobalt treated; (C1 and C2) 10-day peroxide/cobalt treated.

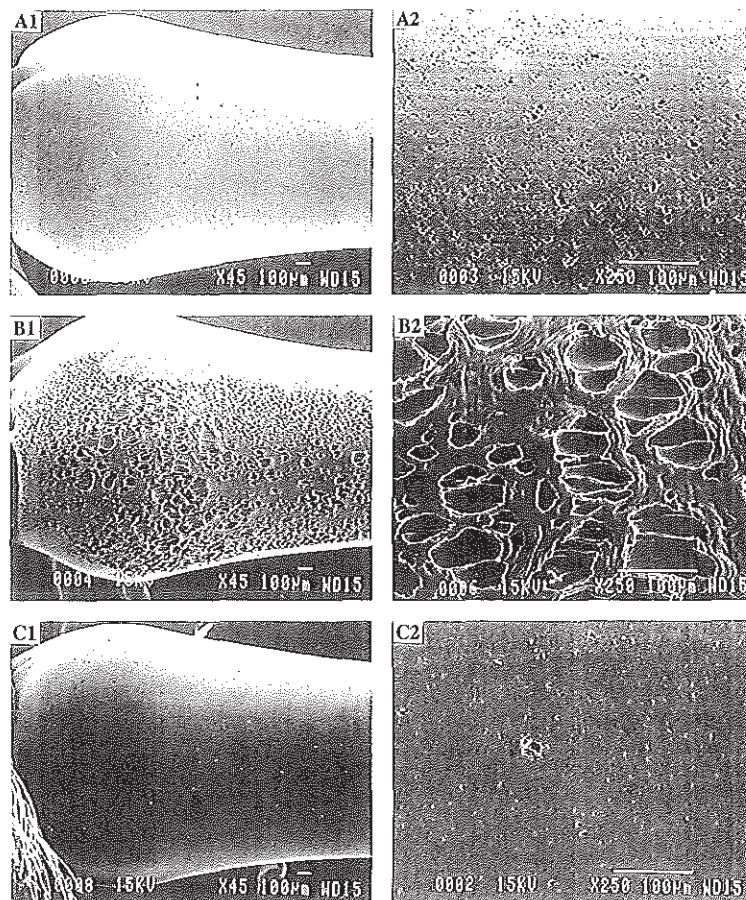


Figure 2. SEM pictures of prestressed specimens after *in vitro* treatments: (A1 and A2) 7 day fraction I plus 9-day peroxide/cobalt treated; (B1 and B2) 7-day fraction II plus 9-day peroxide/cobalt treated; (C1 and C2) 7-day fraction III plus 9-day peroxide/cobalt treated.

The identities of selected proteins were confirmed by immunoblot analysis (Western blot). Briefly, proteins separated by SDS-PAGE were transferred to nitrocellulose (Mini-Transblot, BioRad) for 1 h at 100 V. Nitrocellulose strips were blocked with 5% nonfat dry milk in Tris-buffered saline for 2 h at 25°C prior to application of rabbit primary antibodies to human α_2 -macroglobulin, ceruloplasmin, albumin, or α -fetoprotein (nonspecific control) diluted 1:100 in blocking buffer. After 18 h at 25°C, the strips were washed, incubated with goat anti-rabbit IgG conjugated to alkaline phosphatase (BioRad) for 2 h, washed again, and developed using an alkaline phosphatase substrate kit (BioRad).

RESULTS

SEM surface examination

After 35 days (5 weeks) implantation, severe cracking on the prestressed (strained) Pellethane 80A was observed under SEM [Fig. 1 (A1), (A2)]. The cracking pattern consisted of independent and interconnecting open cracks. The cracks with a fibrillar structure prop-

agated across the tubing surface along the transverse direction of the applied stress. Similar cracking patterns were found on the *in vitro* specimens after the prestressed samples were first treated with plasma at 37°C for 7 days, and then with 10% H_2O_2 (Co) at 50°C for 10 days [Fig. 1 (B1), (B2)]. For the samples treated only in 10% H_2O_2 (Co) solution at 50°C for 10 days, isolated open cracks and brittle microcracking were observed [Fig. 1 (C1), (C2)].

Figure 2 shows SEM pictures of the prestressed specimens respectively pretreated with plasma fractions I, II, and III, then followed by H_2O_2 (Co) treatment. The pretreatment with fraction II [Fig. 2 (B1), (B2)] produced more severe surface cracking on the specimens than the pretreatment with fraction I or III. The cracking on the specimens treated with fraction II plus H_2O_2 (Co) resembled the patterns observed on the 35-day implant [Fig. 1;(A1), (A2)] and the specimens treated with plasma plus H_2O_2 (Co), with large cracks interconnecting and propagating across the surface, whereas the specimens pretreated with fractions I and II showed micro-pitting with no crack propagation.

In Figure 3, the specimens pretreated with α_2 -macroglobulin, α_2 -M [Fig. 3(A1), (A2)] and cerulo-

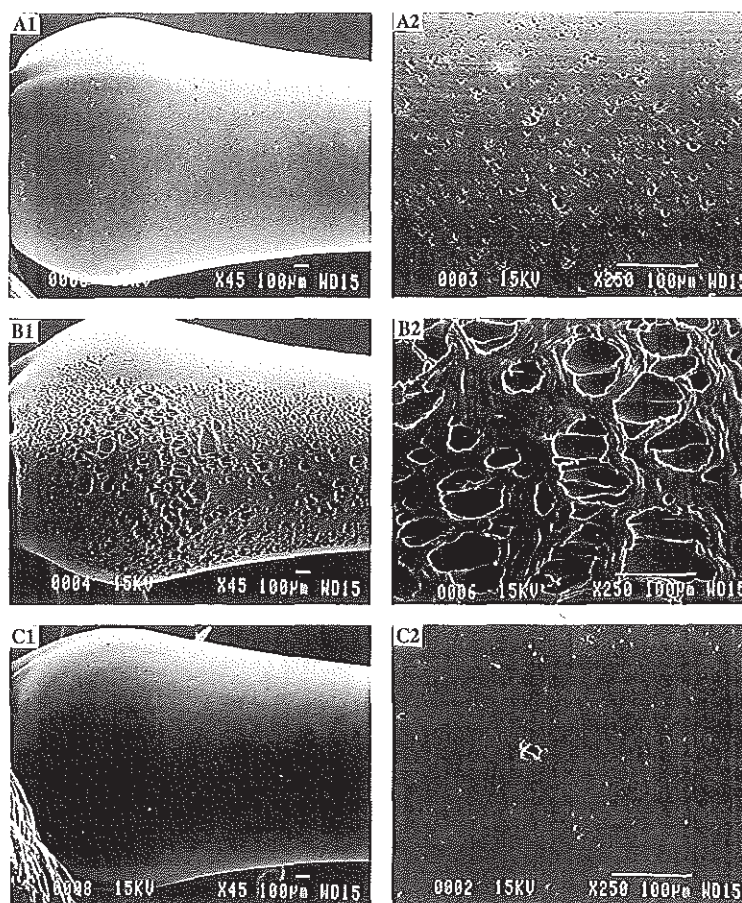


Figure 2. SEM pictures of prestressed specimens after *in vitro* treatments: (A1 and A2) 7 day fraction I plus 9-day peroxide/cobalt treated; (B1 and B2) 7-day fraction II plus 9-day peroxide/cobalt treated; (C1 and C2) 7-day fraction III plus 9-day peroxide/cobalt treated.

The identities of selected proteins were confirmed by immunoblot analysis (Western blot). Briefly, proteins separated by SDS-PAGE were transferred to nitrocellulose (Mini-Transblot, BioRad) for 1 h at 100 V. Nitrocellulose strips were blocked with 5% nonfat dry milk in Tris-buffered saline for 2 h at 25°C prior to application of rabbit primary antibodies to human α_2 -macroglobulin, ceruloplasmin, albumin, or α -fetoprotein (nonspecific control) diluted 1:100 in blocking buffer. After 18 h at 25°C, the strips were washed, incubated with goat anti-rabbit IgG conjugated to alkaline phosphatase (BioRad) for 2 h, washed again, and developed using an alkaline phosphatase substrate kit (BioRad).

RESULTS

SEM surface examination

After 35 days (5 weeks) implantation, severe cracking on the prestressed (strained) Pellethane 80A was observed under SEM [Fig. 1 (A1), (A2)]. The cracking pattern consisted of independent and interconnecting open cracks. The cracks with a fibrillar structure prop-

agated across the tubing surface along the transverse direction of the applied stress. Similar cracking patterns were found on the *in vitro* specimens after the prestressed samples were first treated with plasma at 37°C for 7 days, and then with 10% H_2O_2 (Co) at 50°C for 10 days [Fig. 1 (B1), (B2)]. For the samples treated only in 10% H_2O_2 (Co) solution at 50°C for 10 days, isolated open cracks and brittle microcracking were observed [Fig. 1 (C1), (C2)].

Figure 2 shows SEM pictures of the prestressed specimens respectively pretreated with plasma fractions I, II, and III, then followed by H_2O_2 (Co) treatment. The pretreatment with fraction II [Fig. 2 (B1), (B2)] produced more severe surface cracking on the specimens than the pretreatment with fraction I or III. The cracking on the specimens treated with fraction II plus H_2O_2 (Co) resembled the patterns observed on the 35-day implant [Fig. 1;(A1), (A2)] and the specimens treated with plasma plus H_2O_2 (Co), with large cracks interconnecting and propagating across the surface, whereas the specimens pretreated with fractions I and II showed micro-pitting with no crack propagation.

In Figure 3, the specimens pretreated with α_2 -macroglobulin, α_2 -M [Fig. 3(A1), (A2)] and cerulo-

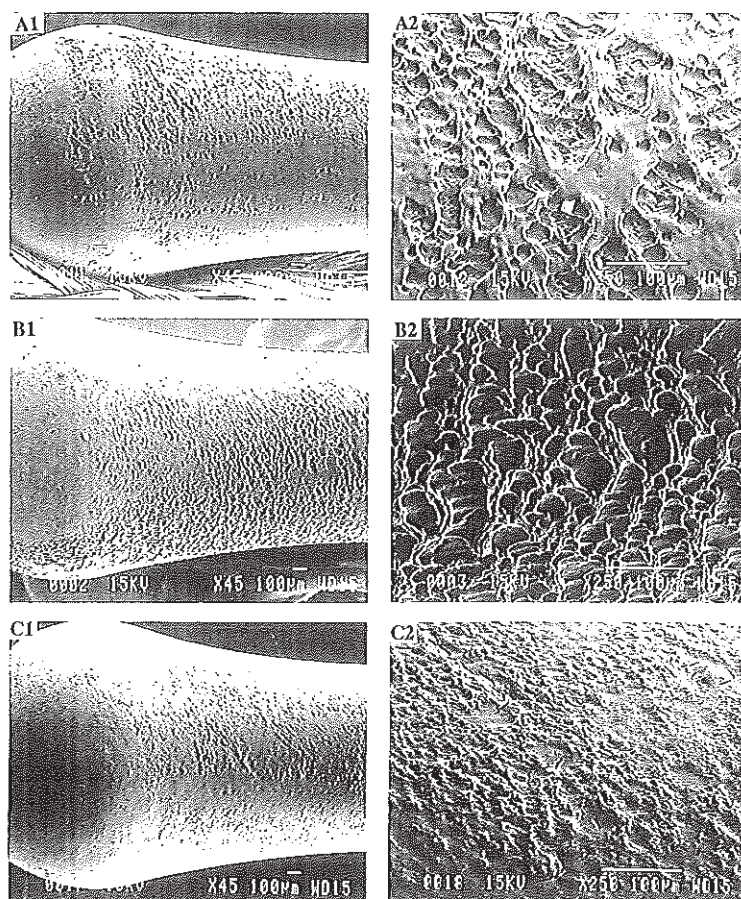


Figure 3. SEM pictures of prestressed specimens after *in vitro*: (A1 and A2) 7-day α_2 -macroglobulin plus 9-day peroxide/cobalt treated; (B1 and B2) 7-day ceruloplasmin plus 9-day peroxide/cobalt treated; (C1 and C2) 7-day lipoprotein plus 9-day peroxide/cobalt treated.

plasmin [Fig. 3(B1), (B2)] solutions showed cracking patterns similar to the specimens pretreated with fraction II [Fig. 2(B1), (B2)]. Surface pitting, roughening, and brittle cracking were observed on the specimens pretreated with lipoprotein [Fig. 3(C1), (C2)]. Similar brittle cracking was also found on the specimens treated with transferrin solution plus H_2O_2 (Co).

ATR-FTIR and GPC analyses

Figure 4 shows the ATR-FTIR spectra obtained from the specimens before and after different treatments. Among the samples, the 7-day plasma-treated samples showed essentially the same spectral features as the untreated samples. Samples treated with H_2O_2 (Co) and plasma plus H_2O_2 (Co), as well as the 70-day (10-week) implant, similarly displayed dramatic changes in their spectra, with large decreases in the soft-segment bands (e.g., 1110 cm^{-1} and 2795 cm^{-1}) and the non-hydrogen-bonded urethane carbonyl band (1730 cm^{-1}). In addition to the decrease in some bands several new bands, were also observed [Fig. 4(A), (B)]. By subtracting the spectra of the treated from the untreated samples, more new bands were revealed. Table III summarizes the new

bands that appeared in the subtracted spectra of the treated samples in the region of $1800\text{--}900\text{ cm}^{-1}$. The new bands were tentatively assigned to the formation of acid, ester, alkene, and aldehyde groups. To support these assignments, bands from some model compounds are listed in Table III.

The experimental and deconvoluted GPC chromatograms for the untreated and treated specimens are shown in Figure 5. By deconvolution two peaks at 15.2 and 18.0 min were revealed in the chromatograms of the untreated and plasma treated bulk specimens [Fig. 5(A), (B)]. For the specimens treated with H_2O_2 (Co) and plasma plus H_2O_2 (Co), the GPC chromatograms showed that, in addition to the two GPC peaks in the untreated, a small peak existed at 23.0–23.5 min [Fig. 5(C), (D)]. Figure 6 depicts the GPC chromatograms of the specimens implanted for 70 days (10 weeks). The *in vivo* specimen had the same peaks found in the untreated polymer, with a small shoulder at 23.0–23.5 min.

The relative percentages of the first, second, and third GPC peaks in the all of the samples are given in Table IV. The percentage of each GPC peak was determined based on the individual peak area compared to the total of all peak areas. The ratios of the

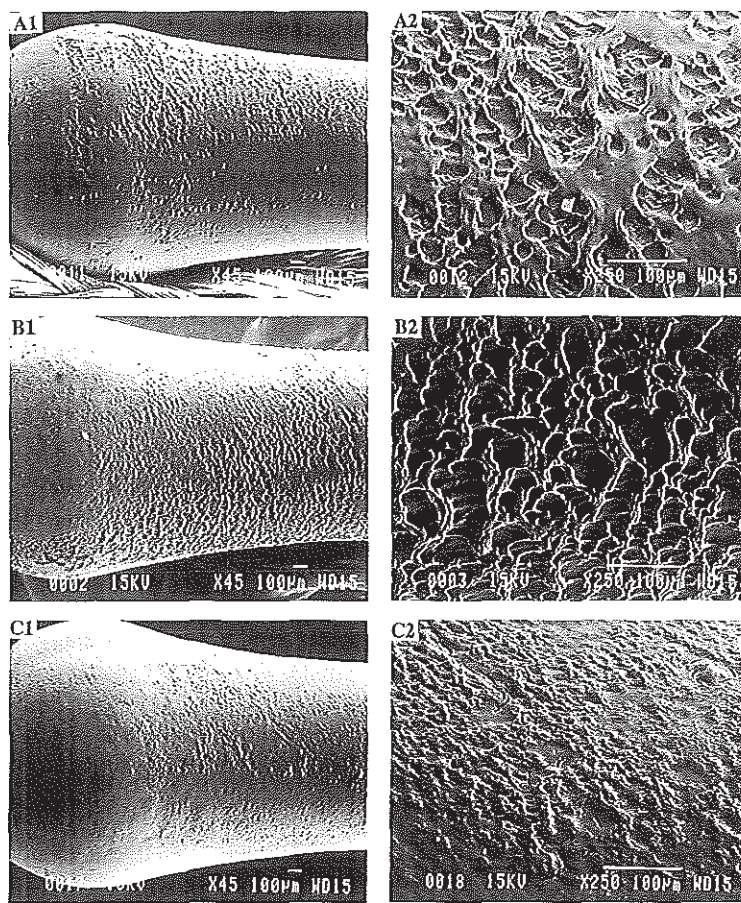


Figure 3. SEM pictures of prestressed specimens after *in vitro*: (A1 and A2) 7-day α_2 -macroglobulin plus 9-day peroxide/cobalt treated; (B1 and B2) 7-day ceruloplasmin plus 9-day peroxide/cobalt treated; (C1 and C2) 7-day lipoprotein plus 9-day peroxide/cobalt treated.

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TABLE III
New Bands in the Subtracted ATR-IR Spectra of Pellethane 2363-80A After *In Vivo* and *In Vitro* Treatments^{a,b}

Bands (cm ⁻¹)	Samples	Intensity	Possible Assignment	Model Compounds ²⁰	
				Name	Band (cm ⁻¹)
~1746	IV	Weak	C=O str, sat. aliph. esters;	Ethyl butyrate	1738
	V	Medium		Ethyl caprylate	1739
1683-1630	III	Medium	C=O str, acids with H-bonding	Fumaric acid	1670
	IV	Weak		Butyl vinyl ether	1635
	V	Medium	C=C str, akenes		
1603-1587%	III	Weak		Maleic acid	1589
	IV	Strong	CO ₂ ⁻ asym. str, acid salts		
	V	Medium			
1402%	III	Strong	C—O str and/or O—H	Butyric acid	1414
	IV	Medium	def, acids CHO in-plane vibr.,	Butyraldehyde	1391
	V	Strong	aldehydes		
1327	III	Weak	C—O str, acids associated O—H def	Succinic acid	1310
	IV	Medium	and C—O str, alcohols C in-plane vibr.,	Butyl vinyl ether	1320
	V	Medium	alkenes		
1285	III	Strong	C—O str and/or O—H def,	Butyric acid	1282
	IV	Strong	acids O—H def and C—O str, alcohols		
	V	Medium			
1230	V	Weak	C—O str, acids associated C—O str,	Butyric acid	1221
			aliph. esters	Ethyl caprylate	1256
1174	III	Strong			
	IV	Strong	C—O—C asym. str, esters	Ethyl caprylate	1175
	V	Strong		Poly(ester urethane) ²¹	1170
930	III	Strong		Butyric acid	938
	IV	Strong	O—H def, acid	Succinic acid	920
	V	Strong			

Note. ^astr = stretching; def = deformation; aliph. = aliphatic.

^bIII, Treated with H₂O₂ (Co); IV, treated with plasma plus H₂O₂ (Co); V, implanted for 70 days.

first and second peaks for all of the samples were similar. The third GPC peak was the highest in the 7-day plasma plus 10-day H₂O₂ (Co)-treated samples. The 70-day *in vivo* sample was the intermediate value, while the 10-day H₂O₂ (Co)-treated samples had the lowest GPC peak area. The molecular weights and molecular weight distributions for each individual peak are shown in Table V. Decreases in molecular weights, M_n and M_w , of the two major GPC peaks were found for the samples treated with H₂O₂ (Co) or plasma plus H₂O₂ (Co). The third peak molecular weights were higher in the 70-day implant than in the specimens treated with H₂O₂ (Co) or plasma plus H₂O₂ (Co).

Adsorbed plasma protein analysis

Figure 7 shows the protein bands on the SDS-PAGE gel obtained from extracts of plasma-treated Pellethane 2363-80A. The standard (column 1) was a solution of proteins with different molecular weights (Bio-Rad). The extraction in 1% SDS solution gave weaker bands in column 2 due to dilution. More striking bands were seen when the extraction was performed in SDS sample buffer (column 3). The bands from the extracts were compared with bands

from commercially obtained purified protein solutions of α_2 -macroglobulin, ceruloplasmin, transferrin, and low-density lipoprotein. It was observed that a band ca. 200,000 molecular weight in the extract coincided with a band from α_2 -macroglobulin. Immunoblotting (Western) with polyclonal antibody to α_2 -macroglobulin indicated a positive band at the same position.

DISCUSSION

In vivo and *in vitro* comparisons

The phenomenon of stress cracking in polyurethanes has been observed in implanted materials or devices.^{8,13} One characteristic of this *in vivo* stress cracking is the nature of ductile fracture in the stressed material, with crack propagation and a fibril pull-out type of crack structure. It was shown in the SEM study that oxidizing a prestressed Pellethane 2363-80A specimens in H₂O₂ (Co) solution alone caused isolated cracks and brittle microcracking, but without crack propagation [Fig. 1(C1), (C2)]. However, when the specimens were pretreated with human plasma and then with H₂O₂ (Co) solution [Fig. 1(B1), (B2)], the cracking became ductile with large open cracks

interconnecting and propagating across the surface along the transverse direction of the applied stress (strain) direction. Morphologically, the pattern of *in vitro* stress cracking had remarkable similarity to that of *in vivo* stress cracking [Fig. 1(A1), (A2)].

Chemical analysis by ATR-FTIR revealed similar chemical changes that occurred after the prestressed specimens were subjected to long-term implantation and *in vitro* treatment with H_2O_2 (Co) or plasma plus H_2O_2 (Co). The oxidative degradation is believed to take place mainly in the poly(tetramethylene ether) soft segments with oxygen radicals attacking either α -methylene or β -methylene groups. This causes a decrease in the intensities of soft-segment bands. Although the attack at the β position is less probable than at the α position, it should be noted that when the polymer is under stress, the activation energy of H-abstraction from the β -methylene is lowered.¹⁴ An attack on α -methylene may result in ester, carboxylic acid, or aldehyde groups, while an attack on β -methylene may result in alcohol, ketone, or alkene. At this point, the formation of some of these functional

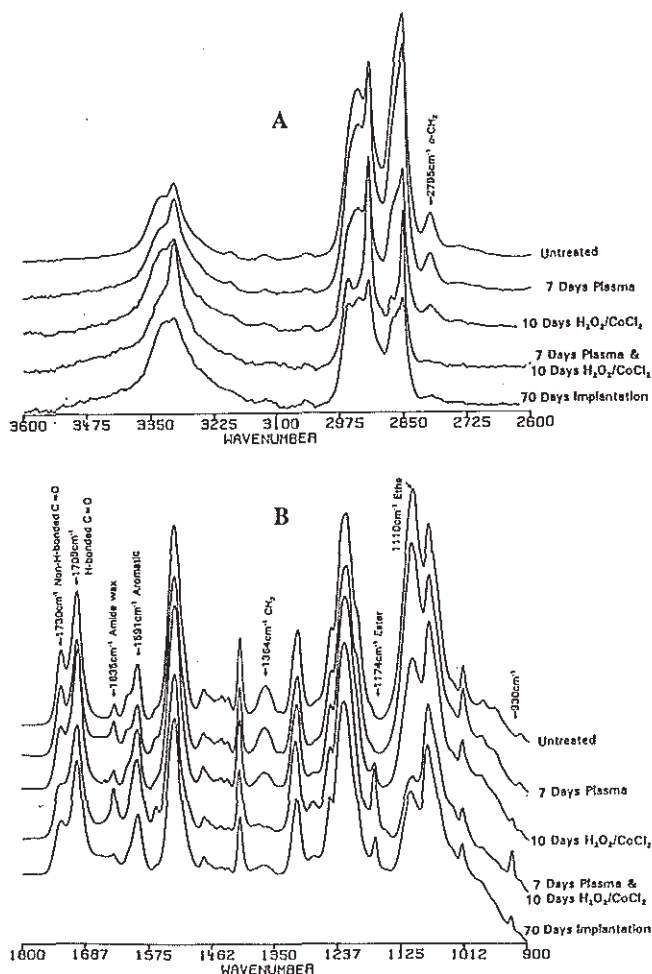


Figure 4. ATR-IR spectra of prestressed specimens before and after different treatments: Untreated; 7-day plasma treated; 7-day peroxide treated; 7-day plasma/9-day peroxide treated; 70 days (10 weeks) implanted.

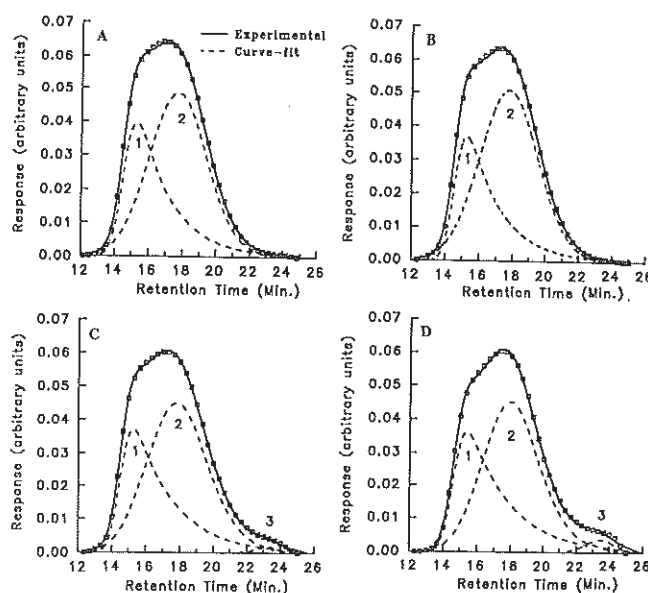


Figure 5. Experimental and deconvoluted GPC chromatograms of prestressed specimens before and after different treatments: (A) Untreated; (B) 7-day plasma treated; (C) 7-day peroxide/cobalt treated; (D) 7-day plasma plus 9-day peroxide/cobalt treated.

groups is strongly supported by comparison of the observed characteristic bands with those of model compounds. For example, the observed acid and ester groups have bands which may be correlated with those of model compounds as shown in Table III. On the other hand, some functional groups, such as aldehyde and ketone, cannot be confirmed spectrally. This means that their formation is either less likely, or that they are less stable, and after their formation they are rapidly oxidized to acid or ester groups by oxygen radicals.

Quantitative comparison of the extent of degradation between different samples can be achieved using depth profile analysis,¹⁵ in which the concentration profile is assumed to change exponentially from surface to the bulk given by $C(x)/C_\infty = (1 - e^{-\delta x})$,

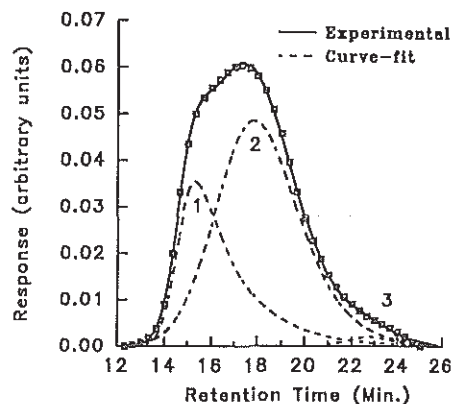


Figure 6. Experimental and deconvoluted GPC chromatograms of a prestressed specimen implanted for 70 days (10 weeks) in a Sprague-Dawley rat in the Cage Implant System.

TABLE IV
Relative Percentage of the Peaks in the GPC Chromatograms Based on the Total Amount of Polymer^a

Sample	% Peak 1	% Peak 2	% Peak 3 _b
Untreated	37.97	62.03	—
7-Day plasma	33.55	66.45	—
10-Day oxidation	38.43	60.70	0.87
7-Day plasma + 10-day oxidation	38.80	59.04	2.16
70-Day <i>in vivo</i>	32.97	65.62	1.41

^aPeak 1 at 15.2 min, Peak 2 at 18.0 min, Peak 3 from 23.0–23.5 min.

^bPercentage of degradation products.

where C_{∞} represents the concentration in the bulk, and δ reflects the concentration change in the depth direction obtainable from the experimental data. A characteristic depth of degradation, Δ , can thus be defined as the depth at which the relative concentration becomes $(1 - e^{-1})$, or $\Delta = 1/\delta$. Since the degradation has been shown to initiate at the surface, the larger the Δ value, the greater the degree of degradation. Table VI lists the Δ values of α -methylene group from the band at 2795 cm^{-1} for samples treated under different conditions. The samples treated with plasma plus H_2O_2 (Co) had the greatest depth of degradation, which was about six times greater than that of the samples treated with H_2O_2 (Co) alone, and about 1.5 times greater than that of the *in vivo* samples. The plasma treated samples showed no degradation effect since the Δ value was about the same as the untreated samples. Thus, it is clear that plasma acts as a catalyst which accelerates the oxidative degradation of the prestressed Pellethane 2363-80A.

The GPC results demonstrated that the bulk samples, when treated with H_2O_2 (Co) or plasma plus H_2O_2 (Co), underwent a degradative process. The presence of two major peaks in the GPC chromatograms of bulk Pellethane 2363-80A indicated

that the polymer contained a bimodal molecular weight distribution. For the untreated samples, the first GPC peak had an M_n of 95,000 and the second peak an M_n of 86,000 relative to polystyrene. After the samples were oxidized for 10 days in H_2O_2 (Co), the first and second GPC peaks decreased in molecular weight and a new peak appeared with an M_n of 3600 relative to polystyrene. Seventy days of implantation caused similar GPC changes in the prestressed specimens. The third peak could result from degradation products. As compared to the 10-day oxidized samples, synergistic effects of plasma plus oxidation caused a further decrease in molecular weights of the first and second peaks and a greater increase in area ratio of the third GPC peak.

Identification of biological stress cracking agents

The fact that the *in vitro* stress cracking of the Pellethane polyetherurethane requires a pretreatment with human plasma prior to H_2O_2 (Co) is intriguing. The effect of plasma plus H_2O_2 (Co) is significantly greater than the effects of plasma alone or H_2O_2 (Co) alone or the additive effects. This suggests that

TABLE V
Comparison of the Molecular Weights and Molecular Weight Distributions of the Prestressed Pellethane 80A Specimens After *In Vivo* and *In Vitro* Treatments^a

Sample	Peak	M_n	M_w	M_z	PDI ^b
Untreated	1	9.51×10^4	5.52×10^6	9.74×10^5	5.80
	2	8.63×10^4	2.78×10^5	1.05×10^6	3.22
7-Day plasma	1	9.48×10^4	5.41×10^5	9.16×10^5	5.71
	2	8.25×10^4	2.78×10^5	1.07×10^6	3.37
10-Day oxidation	1	6.48×10^4	5.13×10^5	9.41×10^5	7.93
	2	5.90×10^4	2.52×10^5	9.43×10^5	4.27
	3	3.66×10^3	4.87×10^3	6.28×10^3	1.33
7-Day plasma + 10-Day oxidation	1	5.10×10^4	4.63×10^5	8.75×10^5	9.02
	2	5.46×10^4	2.11×10^5	6.94×10^5	3.86
	3	3.21×10^3	4.85×10^3	6.99×10^3	1.51
70-Day <i>in vivo</i>	1	7.30×10^4	5.15×10^5	9.23×10^5	7.05
	2	5.70×10^4	2.39×10^5	8.79×10^5	4.21
	3	4.76×10^3	8.13×10^3	1.20×10^4	1.71

^aRelative to polystyrene, UV detector.

^bPolydispersity index.

the role of plasma protein is synergistic with the role of the oxidation to produce ESC. It has been hypothesized that certain biological agents may be involved in the M_n of 86,000 relative to polystyrene. After the samples were oxidized for 10 days in H_2O_2 (Co), the first and second GPC peaks decreased in molecular weight and a new peak appeared with a M_n of 3600 relative to polystyrene. Seventy days of implantation caused similar GPC changes in the prestressed specimens. The third peak could result from degradation products. As compared to the 10-day oxidized samples, synergistic effects of plasma plus oxidation caused a further decrease in molecular weights of the first and second peaks and a greater increase in area ratio of the third GPC peak.

Identification of biological stress cracking agents

It is interesting that the *in vitro* stress cracking of the Pellethane polyetherurethane requires a pretreatment with human plasma prior to H_2O_2 (Co). The effect of plasma plus H_2O_2 (Co) is significantly greater than the effects of plasma alone or H_2O_2 (Co) alone or the additive effects. This suggests that the role of plasma protein is synergistic with the role of the oxidation to produce ESC. It has been hypothesized that certain biological agents may be involved in the stress cracking of polyetherurethane pacemaker insulation during *in vivo* use.^{8,13} We have shown that the *in vitro* stress cracking of prestressed Pellethane specimens is dependent on viable cell/polymer interactions.⁷ Adherent macrophages and foreign-body giant cells on a polyetherurethane urea film *in vivo* can produce oxidative degradation and surface cracking or embrittlement on the material at the cell/polymer contact zones.^{16,17} Based on these findings, our *in vitro* system is designed to mimic the *in vivo* system; human plasma contains certain biological components that can act as a stress cracking promoter, while H_2O_2 (Co) solution provides an oxidative reaction comparable to that observed in the respiratory burst of adherent macrophages and foreign-body giant cells.¹⁸

To identify the biological component(s) in the *in vitro* stress cracking, the plasma was fractionated into three fractions. It was observed that a pretreatment

of the stressed specimens with fraction II caused significant surface cracking where the cracking pattern [Fig. 2(B1), (B2)] resembled the characteristics of *in vivo* stress cracking. Fraction II was dominated by α_2 -macroglobulin (α_2M). To test whether α_2M and/or other proteins could cause a similar effect, commercially obtained purified proteins were reconstituted to physiological concentration and employed to pretreat the prestressed specimens (Table I). Among the selected proteins, pretreatment with α_2M produced the most significant synergistic stress cracking effect [Fig. 3 (A1), (A2)] and pretreatment with ceruloplasmin a moderate effect [Fig. 3(B1), (B2)], whereas pretreatment with low-density lipoprotein or transferrin did not promote crack propagation to the brittle cracks cause by H_2O_2 (Co) oxidation [Fig. 3(C1), (C2)].

Adsorption of human plasma α_2M onto the polyetherurethane was confirmed by SDS-PAGE and immunoblotting. Human plasma α_2 -macroglobulin is a large glycoprotein with four identical subunits of about 185,000 daltons each assembled pairwise by disulfide-bridges.¹⁹ In reducing conditions, SDS-PAGE analysis revealed a protein band migrated slightly ahead of 200,000 dalton molecular weight standard (indicated by the asterisk) in Figure 7. In addition, it was observed that purified α_2M migrated to the same position. Immunoblotting with α_2M specific antibody confirmed the identity of this band to be α_2 -macroglobulin.

CONCLUSIONS

This study demonstrates that the phenomenon of *in vivo* stress cracking in Pellethane 2363-80A is duplicated by an *in vitro* system that involves a pretreatment of the prestressed specimens with human plasma at 37°C for 7 days followed by oxidation in 10% hydrogen peroxide with 0.10M cobalt chloride at 50°C for 10 days. Morphologically, the pattern of *in vitro* stress cracking has remarkable similarity to that of *in vivo* stress cracking with characteristics of ductile failure. Chemical analysis by ATR-FTIR and GPC indicates that *in vitro* and *in vivo* treated samples are degraded by an oxidative reaction that takes place mainly in the polyether soft segments with oxygen

TABLE VI
ATR-FTIR Analysis of Treated and Untreated Pellethane 2363-80A:
Parameters of Degradation Depths for α -Methylene Group at 2795 cm^{-1}

Parameters	Untreated	Treated with Plasma	Treated with H_2O_2 (Co)	Treated with Plasma Plus H_2O_2 (Co)	Implanted for 70 days
K	0.53	0.59	0.57	0.67	—
δ (μm^{-1})	6.1	5.5	2.1	0.32	0.53
Δ (μm)	0.17	0.18	0.47	3.1	1.9
$\Delta T_r/\Delta U_n$	1.0	1.1	2.8	18.8	11.2

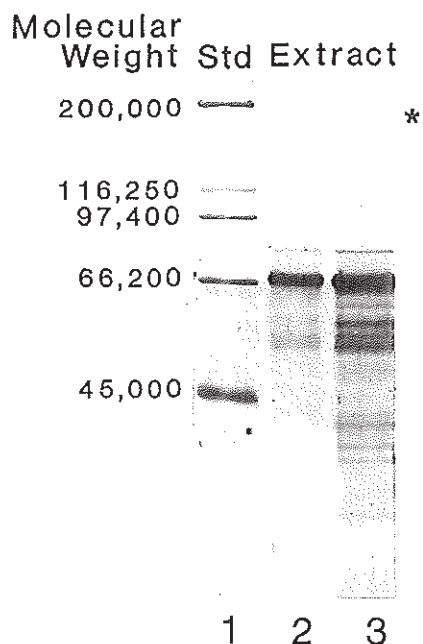


Figure 7. Photograph of SDS-PAGE bands of adsorbed proteins on Pellethane 2363-80A. The protein band indicated by the asterisk is confirmed to be α_2 -Macroglobulin by immunoblotting.

radicals attacking α - and β -methylene groups. *In vitro* pretreatment with plasma has a synergistic effect with the oxidation facilitated by H_2O_2 (Co) treatment to produce ESC.

A plasma component responsible for promoting stress cracking in Pellethane 2363-80A polyurethane is identified to be α_2 -macroglobulin (α_2M). Pretreatment with α_2M -rich plasma fraction or commercially obtained purified protein solution has a significant stress cracking effect on the prestressed specimens. Adsorption of human plasma α_2M onto the polymer is confirmed by SDS-PAGE and immunoblotting.

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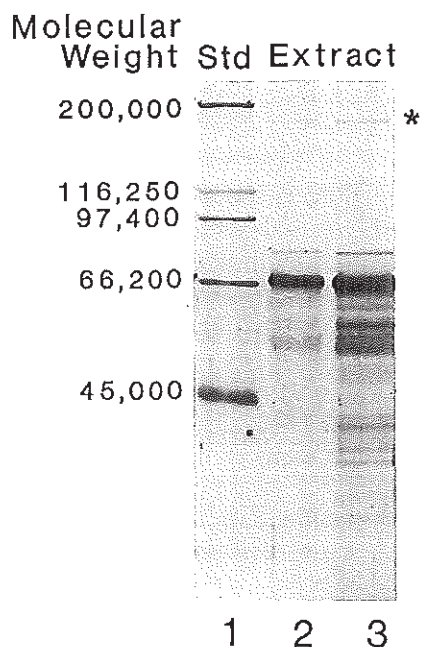


Figure 7. Photograph of SDS-PAGE bands of adsorbed proteins on Pellethane 2363-80A. The protein band indicated by the asterisk is confirmed to be α_2 -Macroglobulin by immunoblotting.

radicals attacking α - and β -methylene groups. *In vitro* pretreatment with plasma has a synergistic effect with the oxidation facilitated by H_2O_2 (Co) treatment to produce ESC.

A plasma component responsible for promoting stress cracking in Pellethane 2363-80A polyurethane is identified to be α_2 -macroglobulin (α_2 M). Pretreatment with α_2 M-rich plasma fraction or commercially obtained purified protein solution has a significant stress cracking effect on the prestressed specimens. Adsorption of human plasma α_2 M onto the polymer is confirmed by SDS-PAGE and immunoblotting.

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EXHIBIT L

Basic science and clinical aspects of mesh infection in pelvic floor reconstructive surgery

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Abstract

Introduction and hypothesis Bacterial colonization following mesh-augmented pelvic floor reconstructive surgery for pelvic organ prolapse is probably an underestimated consideration.

Methods Although clinical infections are rare, subclinical contamination of the polypropylene mesh has been systematically demonstrated by bacteriological analyses during mesh implantation and on explanted meshes.

Results A model of subclinical mesh infection does exist and bacterial colonization and mesh shrinkage have recently been correlated experimentally.

Conclusions New meshes with surface modifications or an antibiotic or antiseptic coating should be explored.

Keywords Polypropylene mesh · Vaginal surgery · Infection · Erosion · Shrinkage

Introduction

Non-absorbable polypropylene meshes are widely used for pelvic floor reconstructive surgery by the vaginal route.

Although they provide appropriate support, their use is restricted by complications of poorly understood origin such as erosion, pain and shrinkage. Many factors have been suspected such as the characteristics of the polypropylene mesh (weight, pore size, stiffness and elasticity), surgical technique, surgeon experience and associated hysterectomy, but even when these factors are controlled, some patients still experience incomprehensible painful shrinkage. Several hypotheses may be put forward to explain this: firstly, an immune reaction to a foreign body [1], but this does not explain the relatively better tolerance of the same material by the abdominal route; secondly, a prolonged inflammatory response (oxidative attack), as previously shown in abdominal hernia [2] and thirdly, a chronic infection.

Our objective is to review the basic science and recent clinical aspects of mesh infection in pelvic floor reconstructive surgery.

Pathophysiology of mesh infection

In other surgical specialities, such as orthopaedics, where the number of patients requiring biomaterials implant surgery is steadily increasing, biomaterials-related infection is one of the main causes of implant failure [3]. In a very interesting paper published by Gristina in *Science* in 1987, it was admitted that one of the major barriers to the extended use of implanted devices is the possibility of bacterial adhesion to biomaterials through the highly adaptive ability of bacteria to colonize the surfaces of “inert” biomaterials or adjacent damaged tissue cells [4]. Biomaterial implantation is followed immediately by a “race for the surface”, a contest between tissue cell integration and bacterial adhesion to that same surface. If

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the bacteria win, the surface is occupied and is thus less available for tissue integration. Furthermore, adhesion-mediated infections are notoriously resistant to antibiotics and host defences, and tend to persist until the biomaterial is removed.

In other words, microorganisms can interfere with the integration process through adhesion to mesh surfaces, and such adhesion is an important stage in the infection [5]. The first stage of adhesion is physical and reversible, but the second is molecular and irreversible [6]. And, it has been suggested that this second stage is dependent upon the adaptative mechanisms of the bacteria itself. A low density of bacteria can produce a protective polysaccharide “bio-film” (slime) that allows the bacteria to remain quiescent. These bacteria may then multiply following an intercurrent event, e.g. an alteration in host immune defences [5]. Chronic infections may therefore appear several months or even several years after mesh implantation [7]. This mechanism of chronic infection may also explain the low bacterial density usually found on explanted meshes [8].

Vaginal surgery is a “clean-contaminated surgery” since the vagina is naturally colonized by bacteria and is located close to the anus. Bacterial contamination may occur when the mesh is initially inserted through faulty asepsis in handling, prepping the vagina or because of the proximity of the anus [8]. Contamination may occur during vaginal closure, when vaginal flora comes in contact with the mesh.

Escherichia coli is common in vaginal infections and is one of the most frequent bacteria responsible for infected biomaterial [4]. Such bacteria on the mesh may also be explained by the conversion of typically non-pathogenic bacteria into virulent colonies adherent to the material [9].

Clinical evidence of mesh infection

Clinical data and experiments have shown that polypropylene is the synthetic material least susceptible to infection and that monofilament should be preferred to multifilament meshes [9]. A large contact area favours bacterial persistence and development in multifilament meshes. As the distance between the filaments is less than 10 μm , bacteria that are around 1 μm in diameter can colonize the mesh, but inflammatory cells (macrophages, neutrophils) are too big to enter [10]. And, whereas the macropores in polypropylene meshes allow inflammatory cells to reach the site of infection [11], microporous suburethral tapes were withdrawn from the market because of the many infectious complications reported [12]. However, even if the rate of clinical infection (periprosthetic abscess) with monofilament, large-pore polypropylene meshes is low (<1%), clinical evidence points to chronic infection occurring frequently.

In a prospective study of 64 consecutive patients undergoing vaginal implantation of a lightweight, collagen-coated monofilament polypropylene mesh, Vollebregt et al. [13] showed that 83.6% of the meshes were colonized by different types of bacteria. These results were obtained using culture swabs of the core mesh during surgery. The rate of bacterial colonization was high despite double disinfection of the surgical area with iodine, prophylactic antibiotic therapy with intravenous cephazolin and metronidazole, a separate drape covering the anal region, a change of gloves and instruments and mesh kept in its sterile pack as long as possible. The bacteria swabbed from the meshes were potentially pathogenic in 13.4% of cases (*Staphylococcus aureus*, *E. coli*, *Bacteroides*, *Enterococcus*, *Proteus mirabilis*), but were present at a very low density (<10³ CFU/mL). Postoperatively, 4.7% of the women presented unexplained fever but none showed any signs of infection up to 6 months later.

The bacteriological analysis of 16 meshes removed because of complications following the surgical management of urinary incontinence or pelvic organ prolapse showed multimicrobial infection in 31% of cases, including *P. mirabilis* (in 25%), *E. coli*, *Staphylococcus*, *Streptococcus* and *Enterococcus* [8]. Bacterial contamination was found in all meshes, even in a case of repeat surgery for mesh shrinkage with no erosion. Bacterial density was low (<10³ CFU/mL) in 43% of cases but in others reached 10⁵ CFU/mL.

Another study reported by Marcus-Braun and von Theobald concerned the retrospective analysis of 83 patients who underwent 104 repeat operations mainly for complete or partial mesh removal [14]. The main indications for mesh removal consisted of erosion ($n=44$) and infection ($n=30$). Among infected cases, only five patients showed abscess (16.7%), and cultures were positive in only seven cases (23.3%), with *E. coli* and *S. aureus* as principal bacteria. In this study, repeat erosion was associated with underlying infection, and recurrent infection was resolved only by complete mesh removal. Furthermore, 66.6% of infections were detected more than 2 years, and some up to 4 years, after mesh implantation.

Clave et al. recently reported on an analysis of 84 meshes explanted for erosion (69%), infection (17%), or shrinkage or pain (14%) [15]. Histological examination revealed mainly two types of periprosthetic tissue reaction, including infection in 44% of cases (altered polymorphonuclear neutrophils) and chronic inflammation in 42% of cases (giant cells and mononuclear cells). A minor contamination process was suspected even in the second type because of the presence of unaltered polynuclear cells associated with partial mesh colonization. Monofilament polypropylene was less frequently associated with infection than multifilament and composite meshes (39% versus

70%, $p=0.02$). Clave et al. reported signs of polymer degradation with polypropylene, particularly in the case of infection (59% of cases).

Finally, several cases of chronic infection due to *Actinomyces israelii* have been reported, particularly in cases of recurrent vaginal erosion following TVT, bone anchored sling and sacrospinous ligament suspension [16–18]. The diagnosis of such an infection requires biopsies of eroded mesh and vaginal tissue around the erosion area for both histological examination and bacterial samples for aerobic and anaerobic culture.

Risk factors for mesh infection

Significant risk factors for mesh infection following ventral hernia repair consist of prolonged operative time [OR 1.38 (95%CI 1.2–1.6)], steroid use [OR 4.15 (95%CI 1.5–11.1)] and smoking [OR 2.46 (95%CI 1.3–4.6)] [19].

In vaginal surgery with mesh, age (>60 years old) and smoking (>6.85 pack years) are associated with vaginal erosion, with relative risks at 1.6 and 3, respectively [20]. Age is responsible for changes in the function of inflammatory cells, reduced extracellular matrix and impaired angiogenesis. Smoking is responsible for vasoconstriction, the formation of microthrombi, decreased fibrinolytic activity and direct endothelial injury. In the same study, smoking was also significantly associated with postoperative infection.

Although other factors such as poor vaginal tissue vascularity, inadequate vaginal tissue coverage and postoperative hematoma are probably also risk factors for infection, there is no evidence for this in the literature. Therefore, no recommendations (such as prolonged antibioprophyllaxis, time to repeat operation) can be made for the management of postoperative hematoma around the mesh or for early mesh exposure.

Mesh infection in an animal model

We have previously described an animal model of mesh infection based on the well-known model of incisional abdominal hernia in Wistar rats. Here, the bacterial inoculate is injected immediately after mesh implantation and skin closure, and a bacterial analysis is performed 1 month later [21]. Such a model could be used to compare the in vivo bacterial infectivity of the different biomaterials used in vaginal surgery. But, such a model must be reproducible and to achieve this, it is essential to control the virulence of the bacteria and the quantity of bacterial inoculate employed. Our model uses strains of uropathogenic *E. coli* whose virulence is tested by polymerase chain

reaction for the presence or absence of a panel of genes encoding known virulence factors (toxins, adhesins, siderophores and capsules). And, with regard to the bacteriological analysis, samples are cultured on Muller–Hinton solution, then tissues are crushed using a sterile scalpel and pots containing the meshes are incubated for 18 h at 37°C.

Rats have already been used in the past to test for the infection of prostheses, but excision was in all cases early, on day 7 [9, 22]. We chose late explantation 30 days after surgery, and this is for two reasons. First, we considered it important to wait until after the immediate inflammatory reaction, and, second, postoperative complications due to meshes implanted by the vaginal route seldom occur soon after surgery. We chose to inoculate animals with *E. coli* as this bacterium is often implicated in urogenital infections and often colonizes the vaginal mucosa. It may become offensive, acquiring pathogenic islets that include genes coding for a variety of virulence factors (toxins, siderophores and capsules). In our first experiment, the persistent infection of all meshes on day 30 with the same *E. coli* validated our decision to use this bacterium. Yet, culture swabs were polymicrobial, with mainly commensal microorganisms (*Staphylococcus epidermidis*, *Corynebacteriae*) or colonizing saprophytes (*S. aureus*). *P. mirabilis* was the only pathogenic bacteria, and may have been the consequence of surgical contamination. We chose model parameters in such a manner to result in the slightest possible infection of the mesh for infection in clinical practice probably arises from involuntary contamination with a small number of microorganisms. In confirmation of this, when meshes are removed because of clinical complications (erosion, infection) and cultured, only a low bacterial density is usually found. Our minimal infection of the mesh therefore more closely matches clinical conditions.

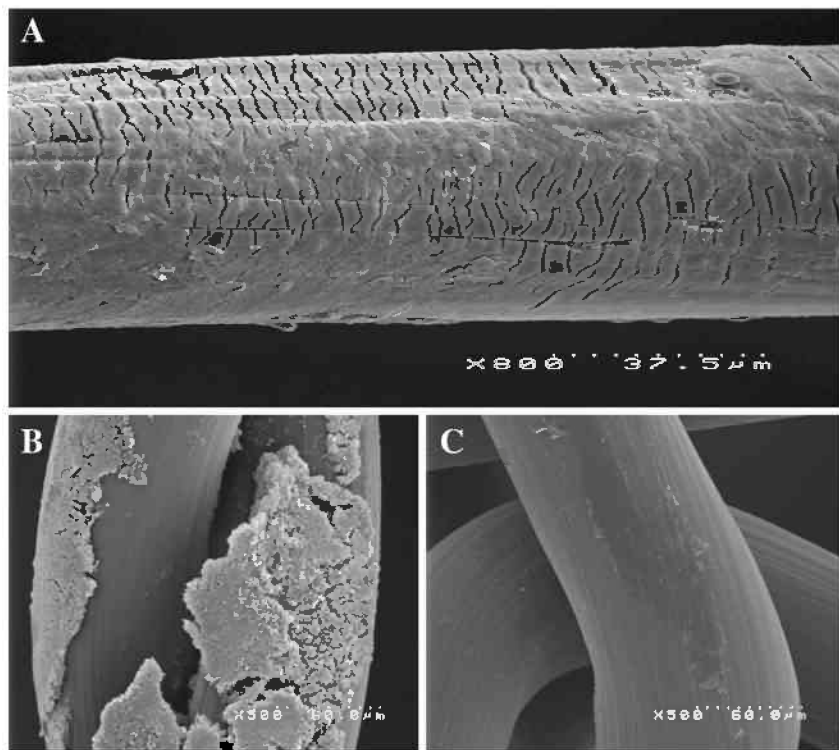
What have we learned from basic science?

A subclinical mesh infection, acquired during the initial implantation, may result in wound separation with subsequent mesh exposure [23].

If vaginal erosion is detected, it raises the question of whether mesh colonization is a risk factor for erosion, or whether erosion exposes the mesh to vaginal bacteria that then colonize it [13].

In a recent study, we put forward the hypothesis that mesh infection stemming from bacterial contamination during the implantation phase is an independent risk factor for shrinkage [24]. A low concentration of bacterial cells (10^6 CFU) was injected onto the mesh intraoperatively in order to mimic subclinical bacterial contamination. A significant correlation was observed between infection and shrinkage.

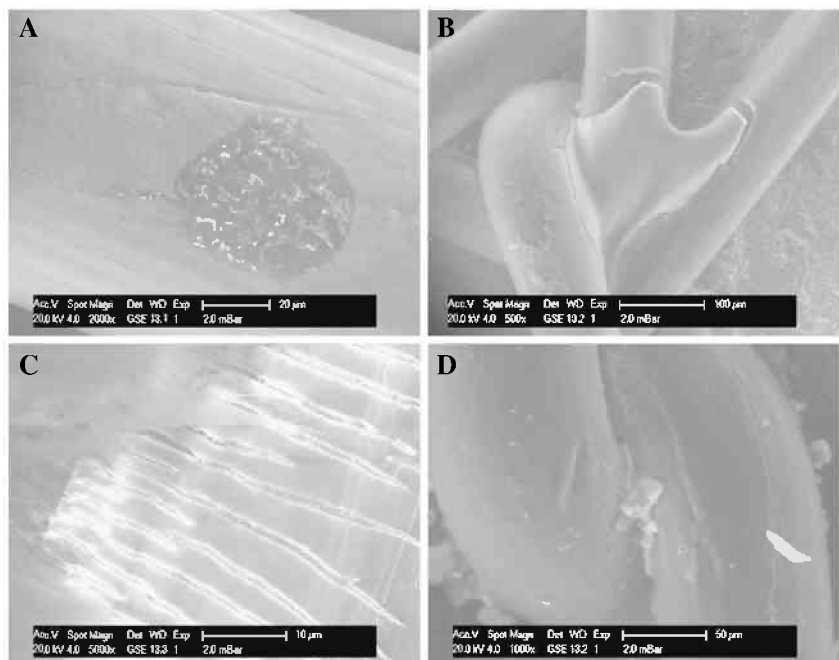
Fig. 1 Scanning electron microscopy of low-weight, macroporous, monofilament knitted polypropylene mesh extracted after 30 days with infection by *E. coli* in an incisional abdominal hernia model in Wistar rats. The explanted infected mesh shows transverse cracks (a). After washing with DMSO (b) and ultrasonic shock (c), it appears marked modifications in mesh surface corresponding to the biofilm (a), and after biofilm removal, no polymer degradation was seen any more (c)



Using the same model of mesh infection, we also experimentally tested Clave's conclusion [15] regarding a correlation between infection and polypropylene "degradation". Polypropylene meshes were implanted in the incisional abdominal hernia model in Wistar rats and inoculated with 10^6 CFU of *E. coli*, as described previously [24]. After 30 days the meshes were explanted and washed with dimethyl sulfoxide (DMSO) and ultrasonic shock, then

examined by environmental scanning electron microscope (ESEM). At the same time, polypropylene meshes were inoculated in vitro with the same isolate of *E. coli*, then explanted after 2–15 days and washed with the same process. In these studies we also observed signs of superficial degradation and transverse cracks (Figs. 1 and 2), but this appeared to concern only the biofilm, with no effect on the implant thread itself (unpublished data).

Fig. 2 ESEM of in vitro infection of low-weight polypropylene macroporous knitted mesh extracted from a bacterial culture medium infected by *E. coli* after 2 (a), 5 (b) and 15 days (c). a Beginning of biofilm formation. b Cracks in the biofilm at mesh interstices. c Transverse cracks in the biofilm. d Non-degraded polymer thread after washing out the biofilm



Perspectives

Although the short- to medium-term risk of infection and subsequent erosion, shrinkage or repeat operation for partial or complete mesh removal is now better understood, knowledge is still lacking for the long term. Recently, two case reports, one concerning an enterocutaneous fistula 14 years after prosthetic mesh repair of a ventral incisional hernia [25] and the other a suprapubic vaginocutaneous fistula 18 years after a bladder-neck suspension [26], were interviewed if pelvic reconstructive surgery using polypropylene mesh by the vaginal route is a lifelong risk.

Tissue ingrowth around synthetic implants is a complex phenomenon, indissociable from the inflammatory reaction. An immunochemical analysis of infected implanted mesh would be of great interest, with a particular focus on transforming growth factor (TGF)- β 1 which is a determinant of foreign body reaction to alloplastic materials in rat fibroblast cultures [27]. This type of study should be able to differentiate between the respective responsibilities in mesh shrinkage of bacterial contamination and non-infectious foreign body reactions. Should the hypothesis be confirmed, the use of antibacterial products on synthetic implants would be greatly beneficial in women.

Antibiotics may be used protectively during the initially vulnerable period before the surface is stabilized, when random colonization by bacteria might occur [4]. Parallel to the potential advantages of coating with antibiotics, silver coated-mesh has been shown to reduce bacterial colonization around the mesh [28].

Biomaterial surfaces must be modified to improve compatibility and tissue integration, and resist microbial colonization in the “race for the surface” [4]. Modifications of the mesh surface, such as brush coating, have been shown to be effective in reducing the development of a less mature and less organized bacterial biofilm, resulting in decreased bacterial contamination of the implant [3]. With no antibiotic or antiseptic on the mesh, this simple physicochemical modification could give prophylactic intravenous antibiotics a better chance of killing any bacteria that have adhered to a brush-coated implant surface during surgery, and this prior to the formation of a more mature and thus more resistant biofilm.

Conclusion

Bacterial colonization following mesh-augmented pelvic floor reconstructive surgery for pelvic organ prolapse is probably an underestimated consideration. Prolonged inflammatory response and chronic infection could be two different mechanisms, which may coexist, explaining local complications such as painful shrinkage. However, the exact role of

infection must be explored by further experimental and clinical studies.

Conflicts of interest None.

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EXHIBIT M



ORIGINAL ARTICLE

The myth: in vivo degradation of polypropylene-based meshes

Shelby F. Thames¹ · Joshua B. White² · Kevin L. Ong²Received: 20 May 2016 / Accepted: 18 August 2016
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Abstract

Introduction and hypothesis Polypropylene is a base polymer used in biomaterial applications, including sutures and mesh products, for the treatment of pelvic organ prolapse, stress urinary incontinence, and hernia repairs. Previous studies have dismissed the value of formulation additives employed in polypropylene, and the importance and necessity of an effective mesh explant cleaning protocol when characterizing explanted devices. However, both are critical to understanding the alleged degradation of polypropylene-based meshes.

Methods An effective, nondestructive, hydrolytic cleaning process, supplemented with light microscopy (LM), Fourier transform infrared spectroscopy (FTIR), and scanning electron microscopy (SEM) data, was used to evaluate 78 explanted Prolene meshes (with duration of implantation ranging from 0.4 to 11.7 years).

Results The cleaning process exposed clean, unoxidized, nondegraded Prolene fibers with smooth surfaces and with no visible evidence of gradient-type or ductile damage. LM showed identical translucent and sometimes clear, cracked/flaking material on both blue and clear fibers, instead of clear cracked/flaking material on the clear fibers and blue cracked/flaking material on the blue fibers. FTIR confirmed progressive protein removal and loss of protein absorption intensity after each cleaning step.

Conclusions Our effective cleaning of explanted Prolene meshes and subsequent analyses showed that they did not

degrade in vivo, confirming the in vivo stability of properly formulated polypropylene. Instead, the cracked layer that some researchers have identified as degraded Prolene is an adsorbed protein–formaldehyde coating, resulting from the well-established formalin–protein fixation process, which occurs immediately upon placing an explant in formalin.

Keywords Polypropylene · Mesh · Explant analysis · Stability · Formalin fixation

Introduction

The polymer polypropylene (PP) is the basic building block of surgical mesh products used for hernia repair in addition to pelvic organ prolapse (POP) and stress urinary incontinence (SUI). In the early 1960s, Usher began using PP surgical meshes for the treatment of hernias, thus changing the approach for treating abdominal wall defects [1] and subsequently other tissue repair procedures. The use of PP for urogynecological repairs was reported for surgeries in the late 1960s, and became more popular for POP [2] and SUI with the introduction of tension-free vaginal tape (TVT) in the 1990s [3]. The American Urogynecology Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction (SUFU) [4] have even stated that the use of PP midurethral slings is not only the recognized worldwide standard of care for the surgical treatment of SUI, but it is safe and effective, and has improved the quality of life for millions of women. They further noted that polypropylene mesh is widely studied and recognized as being safe and effective as a surgical implant.

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Over the past few years, a number of researchers have claimed that PP is not stable in vivo, but rather is oxidized and consequently experiences a loss of molecular weight, deterioration of physical properties, embrittlement, chain scission, the generation of carbonyl-containing byproducts, and in general, results in an overall loss of efficacy [5–12]. These researchers based their conclusions on the observation of a cracked layer on PP fibers, claiming that infrared spectroscopy demonstrated the presence of oxidative species and the absorption of histological dyes by pathological specimens. However, these studies failed to consider the natural adsorption of biological material when medical devices come into contact with bodily fluids [13], and the reaction of fixatives with biological materials coating the devices [14–16], thereby creating a polymerized proteinaceous layer covering the fiber (Fig. 1). They also either do not attempt to remove or do not adequately remove biological materials, which are generally fixed in formalin, from the devices. Formalin fixation may further affect chemical analysis, because it can shift and alter the intensity of absorptions in Fourier transform infrared spectroscopy (FTIR) analysis of tissue [17].

It is well documented that unstabilized PP oxidizes readily under ultraviolet (UV) light and upon exposure to high temperatures [18]. The well-known end results of PP oxidation are the formation of carbonyl compounds, molecular weight loss, and significant degradation of physical properties. However, properly formulated PP with high performance additives is stable in oxidizing media, including elevated temperatures, in vivo applications, and to a lesser extent, under UV light. For example, although Liebert et al. [19] reported the oxidation of unstabilized PP, his 1976 manuscript also established the profound stabilizing effects of antioxidants.

Liebert's work was followed by that of Williams, who reviewed polymer degradation in physiological environments [20]. He referenced Liebert, concluding that "activation energies for the degradation of high molecular weight polymers used in surgery vary from 30 kcal mol⁻¹ to 80–90 kcal mol⁻¹ and such reactions generally require heat, UV light, or high energy radiation, preferably in the presence of oxygen, to proceed. It seems certain from these conditions that no such degradation

should occur within the confines of the human body." Williams followed with a 1992 *Clinical Materials* article, stating that "hydrophobic homochain polymers should be stable under in vivo conditions" [21].

Publications have identified a cracked surface on explanted polypropylene meshes and strongly attributed its presence to in vivo oxidation. However, the associated compositional analysis has been limited and inconclusive [5–12]. Given the limitations of previous explant studies, the purpose of the present study was to analyze the morphology and material chemistry of explanted Prolene urogynecological meshes cleaned via a novel and effective cleaning process.

Materials and methods

Explanted Prolene (Ethicon, Somerville, NJ, USA) meshes ($N=78$) were obtained as part of medicolegal proceedings. The repository included eight different mesh designs for SUI or POP applications with implantation duration ranging from 0.4 to 11.7 years (Table 1). Twelve explants were received dry, whereas the remaining 66 explants were received in fixative. The explants were stored for an additional 0.1 to 6.4 years before cleaning and analysis. Institutional Review Board approval (Exponent, Philadelphia, PA, USA) was received for this study. Exemplar Prolene meshes (Ethicon) were also cleaned and analyzed to serve as control samples (TVT, $n=8$; TVT Secur, $n=3$; TVT Abbrevio, $n=1$; Gynemesh, $n=3$; Prolift, $n=6$; Prolift + M, $n=3$; Prosima, $n=1$; and Prolene mesh, $n=1$).

To reverse the well-known chemistry of fixative crosslinking, the meshes were cleaned using a process that exposed them to several reagents under varying conditions (Fig. 2). The cleaning process started with an initial distilled water soak; later rounds of cleaning used combinations of incubations in distilled water at an elevated temperature (70–80 °C) [15, 22], agitation using ultrasonication (with or without previous use of an orbital shaker) with sodium hypochlorite (bleach or NaOCl) [23], incubation in a proteinase K solution (enzymatic digestion) at an elevated temperature (58 °C) [14, 22], and corresponding treatment by ultrasonication in proteinase K. The meshes were rinsed to

Fig. 1 Protein–formaldehyde "fixation" reaction

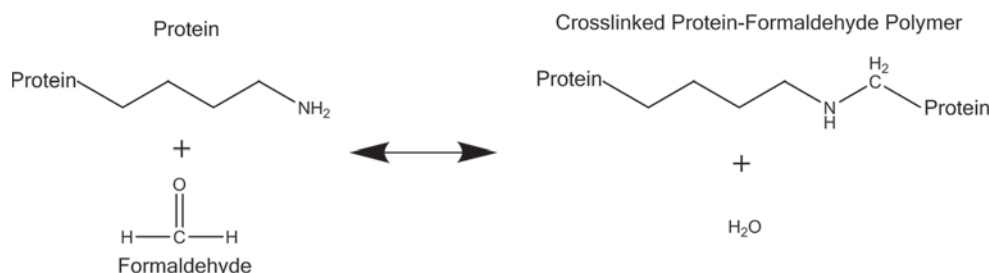


Table 1 Explant summary

Patient number	Explanted Prolene mesh	Duration of implantation (years)	Duration of storage (years)	Condition explants were received in
001	TVT	7.8	0.1	Fixative
002	TVT	2.3	4.5	Fixative
003	TVT Abbrevio	0.5	4.0	Fixative
004	Prolift	7.4	1.9	Fixative
005	Prolift	2.2	4.2	Fixative
006	Prolift	4.4	2.9	Fixative
007	TVT	9.4	3.0	Dry
008	TVT	2.0	3.7	Dry
009	Prolift	4.4	3.5	Fixative
010	Prolift	4.1	3.8	Fixative
011	Prolift	3.9	3.7	Dry
012	TVT	9.3	3.6	Fixative
013	Gynemesh	9.0	0.2	Fixative
014	TVT	5.3	2.4	Fixative
015	TVT	4.2	4.2	Fixative
016	TVT	5.2	4.3	Fixative
017	Gynemesh	2.1	3.0	Dry
018	Prolift	6.4	1.2	Fixative
019	Prolift	4.8	2.0	Fixative
020	TVT	4.6	1.0	Fixative
021	Prolift	4.0–4.3 ^b	3.3	Fixative
022	Prolift	7.3	1.7	Fixative
023	Prolift	4.0	3.7	Fixative
024	Prolift	4.1	2.7	Fixative
025	Prolift	5.9	2.0	Dry
026	Gynemesh	4.6	6.4	Fixative
027	Prolift	7.1	0.2	Fixative
028	TVT	5.2	0.9	Fixative
029	Prolift, TVT Secur	6.3	1.5	Fixative
030	Prolift + M	5.8	0.1	Fixative
031	Prolift + M	2.1	3.8	Dry
032	TVT	2.4	5.7	Fixative
033	Gynemesh	4.2	3.7	Fixative
034	TVT	2.6	0.1	Fixative
035	Prolift	3.0	2.0	Fixative
036	TVT	2.6	2.3	Fixative
037	Prolift	4.7	2.1	Dry
038	Gynemesh	11.7	1.2	Fixative
039	TVT	3.7–4.7 ^c	0.1	Fixative
040	Prolift + M	1.9	1.7	Fixative
041	Prosima	3.1	0.7	Fixative
042	TVT	4.5	0.2	Fixative
043	TVT	6.0	0.4	Fixative
044	Prolift, TVT Secur	7.4	0.3	Fixative
045	Prolift	2.7	2.2	Dry
046	Prolift	8.0	1.0	Fixative
047	Prolift + M	1.1–2.4 ^d	2.8–4.1 ^d	Fixative (<i>n</i> = 2)
048	Prolift + M	5.8	1.2	Fixative
049	Gynemesh	3.2	1.6	Fixative
050	?? ^a	?? ^a	2.9	Fixative
051	TVT	9.8	3.1	Fixative
052	Prolift	3.1	4.0	Fixative
053	Prolift, TVT Secur	5.8	3.2	Fixative
054	TVT	1.8	4.7	Dry
055	TVT	1.3	4.7	Fixative
056	TVT	2.1–8.1 ^d	0.1–6.0 ^d	Dry (<i>n</i> = 1)/fixative (<i>n</i> = 1)
057	TVT	6.3	3.9	Fixative
058	Prolift	4.3	4.0	Fixative
059	Prolift, TVT	2.8	4.5	Fixative
060	Prolift	4.8	2.8	Fixative
061	TVT	0.4	4.3	Fixative
062	TVT	2.5	4.3	Fixative
063	TVT	5.8	1.1	Fixative
064	Prolift	7.6	0.1	Fixative
065	Prolift	3.8	3.6	Fixative

Table 1 (continued)

Patient number	Explanted Prolene mesh	Duration of implantation (years)	Duration of storage (years)	Condition explants were received in
066	Prolift	2.3	4.2	Fixative
067	Prolene mesh	9.4	4.1	Fixative
068	Prolift	4.9	3.9	Fixative
069	TVT	6.2	2.0	Fixative
070	TVT	6.8	3.5	Fixative
071	Prolift	4.4–6.7 ^d	1.0–3.3 ^d	Fixative (<i>n</i> = 2)
072	Gynemesh	2.3	3.7	Fixative
073	TVT	6.9	0.2	Fixative
074	TVT	10.3	2.6	Dry
075	TVT	4.6	2.5	Dry

TVT tension-free transvaginal tape

^a The operative report for the implantation surgery was not available for review

^b Devices were implanted on two dates

^c Only the year of implantation was available

^d Devices were explanted on two dates

remove residual reagent solution from the samples after each intermediate cleaning step and before conducting materials analysis. The cleaning process shown was used for the

majority of explants (85 %; 66 out of 78) analyzed; this evolved from earlier iterations of the protocol, which had used fewer steps (e.g., two cleaning cycles of NaOCl instead of

Fig. 2 Explant and exemplar cleaning protocol

Before Cleaning Rinse				
1st Step	2nd Step	Before Cleaning		
Distilled water. Rinse; soak 1h; rinse	Desiccation drying, 1h	Materials Characterization		

Cleaning Sequence #1				
3rd Step	4th Step	5th Step	6th Step	After Cleaning 1
Distilled water. Water bath (70°C-80°C), up to one day	NaOCl. Shaker, 5 min to 6.5h (depending on bulk tissue)	Distilled water. Rinse; soak 1h; Rinse	Desiccation drying, 1h	Materials Characterization

Cleaning Sequence #2				
7th Step	8th Step	9th Step	10th Step	After Cleaning 2
Distilled water. Water bath (70°C-80°C), up to one day	NaOCl. (1.5-2h) (shaker/ ultrasonicator)	Distilled water. Rinse, ultrasonic bath 1h, rinse	Desiccation drying, 1h	Materials Characterization

Cleaning Sequence #3				
11th Step	12th Step	13th Step	14th Step	After Cleaning 3
Distilled water. Water bath (70°C-80°C), up to one day	NaOCl. (4-6h) (shaker/ ultrasonicator)	Distilled water. Rinse, ultrasonic bath 1h, rinse	Desiccation drying, 1 h	Materials Characterization

Cleaning Sequence #4					
15th Step	16th Step	17th Step	18th Step	19th Step	After Cleaning 4
Distilled water. Water bath (70°C-80°C), up to one day	0.8 mg/ml Proteinase K. Water bath (58°C), up to one day	0.8 mg/ml Proteinase K. Ultrasonic bath, 2 h	Distilled water. Rinse, ultrasonic bath 1h, rinse	Desiccation drying, 1 h	Materials Characterization

Cleaning Sequence #5				
20th Step	21st Step	22th Step	23rd Step	After Cleaning 5
Distilled water. Water bath (70°C-80°C), 8 h	NaOCl. (4-20h) (shaker/ ultrasonicator)	Distilled water. Rinse, ultrasonic bath 1h, rinse	Desiccation drying, 1 h	Materials Characterization

four), additional reagents (e.g., nitric acid), and different cleaning durations.

At each intermediate cleaning step, explanted meshes and exemplar meshes underwent materials characterization and the data from the respective cleaning steps were designated as follows: Before Cleaning, After Cleaning 1, After Cleaning 2, After Cleaning 3, After Cleaning 4, and After Cleaning 5. The characterization performed at each step included light microscopy (LM), Fourier transform infrared microscopy (FTIR-Micro), and scanning electron microscopy (SEM). This technique allowed fiber examination after each step, thereby confirming loss of adhered proteins in a sequential fashion.

Light microscopy was performed using a Keyence VHX-600 digital microscopy system (Itasca, IL, USA). FTIR spectroscopy was conducted in transmission mode [24] with 64 scans at 2 cm^{-1} resolution using a Thermo Nicolet 6700 FTIR equipped with a Continuum™ Infrared Microscope (Thermo Fisher Scientific, Waltham, MA, USA). SEM imaging was performed via variable pressure mode using a Zeiss Sigma VP FEG-SEM (Carl Zeiss Microscopy, Jena, Germany) and a FEI Quanta 600 FEG (FEI, Hillsboro, OR, USA).

Results

Initial examination of the explants showed varying amounts of bulk tissue adhering to the sample after removal from the patient. Some explants were heavily covered in tissue and mesh fibers could only be observed if they protruded from the dissected edges of the specimens; other samples had less tissue adherence following explantation and mesh fibers were either clearly visible through the bulk tissue or were exposed (Fig. 3).

Fig. 3 Overall optical microscopy images of explant samples from patients 017 (top left), 014 (top right), 022 (bottom left), and 021 (bottom right). Patient samples had varying amounts of bulk tissue and exposed mesh fibers before cleaning. Image magnification: $\times 20$

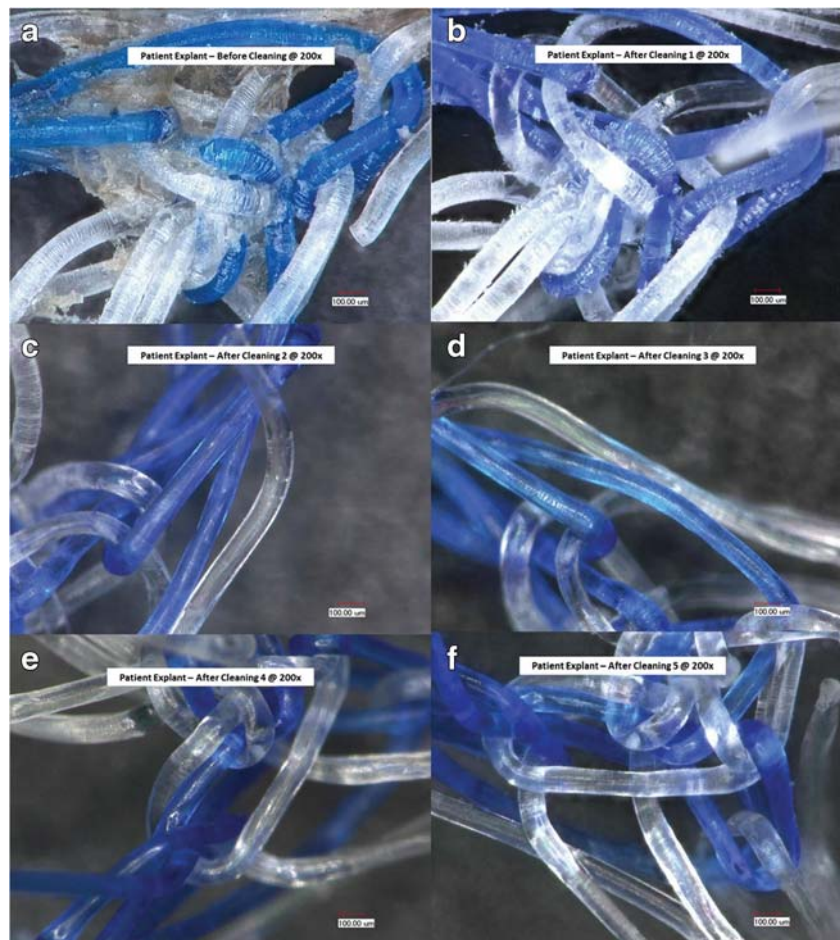


Light microscopy evaluation showed identical translucent and sometimes clear, cracked/flaking material on both blue and clear fibers (Fig. 4), instead of clear cracked/flaking material on the clear fibers and blue cracked/flaking material on the blue fibers. This observation was consistent across all explants containing blue fibers.

The “Before Cleaning” FTIR spectra (Fig. 5) showed spectral components of proteins as noted by the prominent $3,299$ - and $1,652\text{-cm}^{-1}$ frequencies and polypropylene via absorption frequencies at $1,452$ and $1,379\text{ cm}^{-1}$. The protein frequencies are due to amide N-H stretching in the $3,300\text{-cm}^{-1}$ region, and amide I carbonyl stretching in the region of $1,600$ – $1,690\text{ cm}^{-1}$ [25]. FTIR data confirmed protein removal after each cleaning step for the explants’ blue and clear Prolene fibers (Fig. 6), as demonstrated by the progressive loss of protein absorption intensity. This was confirmed via LM (described previously) and SEM (described later). The effectiveness of the cleaning process was further illustrated by overlaying the FTIR spectra of the exemplar fibers and explant fibers after the final cleaning step (Fig. 7).

In the Before Cleaning step in the Prolene explant, fibers were surrounded by bulk tissue and encased in a dry and cracked proteinaceous layer, as observed on explant surfaces via SEM (Fig. 8). In some locations, the bulk tissue had peeled from the cracked layer, exposing two surfaces that had once been a contiguous layer (see “lock and key” morphology of the tissue and cracked layer). The observable “lock and key” pattern of the formalin–protein coating demonstrated cohesive failure of the composite coating and partial adhesive failure of this same composite layer. The proteinaceous structure of the cracked layer and bulk tissue was confirmed by FTIR-Micro (described above). Cleaning progressively removed the bulk tissue and the proteinaceous shell surrounding the Prolene

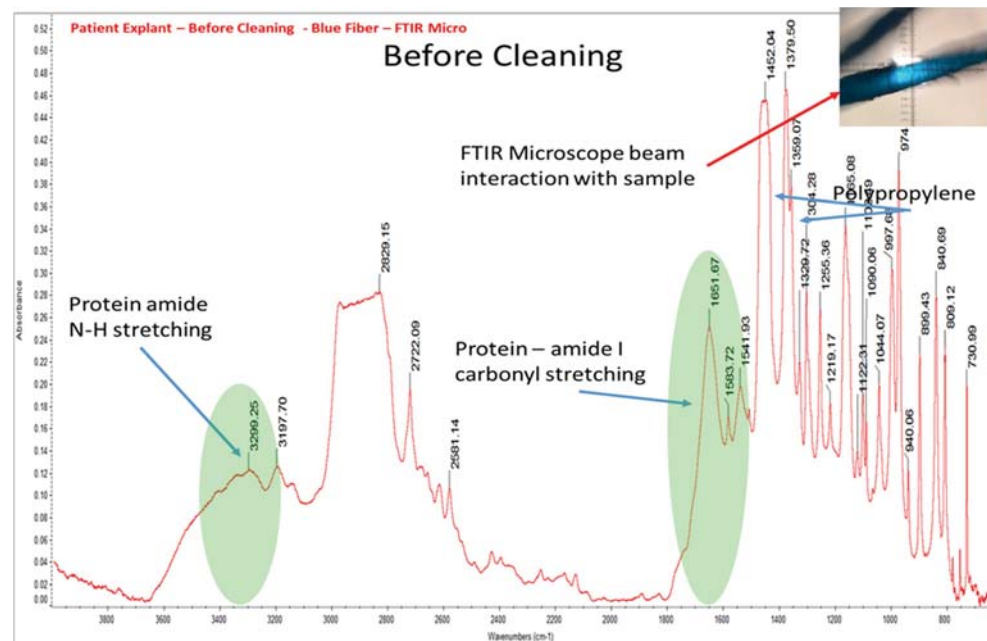
Fig. 4 Patient 033 explant: **a** before and **b–f** after various cleaning steps. Image magnification: $\times 200$. Had Prolene been oxidized, blue fiber flakes would be blue and clear fiber flakes would be clear; instead, identical translucent/sometimes clear, cracked and flaking material residue on both blue and clear fibers. The light microscopy images also demonstrate the successive removal of tissue using the cleaning protocol



fibers. The cleaning process exposed clean, unoxidized, nondegraded Prolene fibers with smooth surfaces and with no visible evidence of gradient-type or ductile damage

(Fig. 9). The cleaned fibers retained the manufacturing extrusion lines created during fiber manufacture similar to those found with the exemplar meshes (Fig. 10). Generally, the

Fig. 5 Patient 033 explant: blue fiber Fourier transform infrared spectroscopy (FTIR) before cleaning. Protein frequencies for the amide N-H stretching in the $3,300\text{-cm}^{-1}$ region and amide I carbonyl stretching in the region of $1,600\text{--}1,690\text{ cm}^{-1}$ were observed



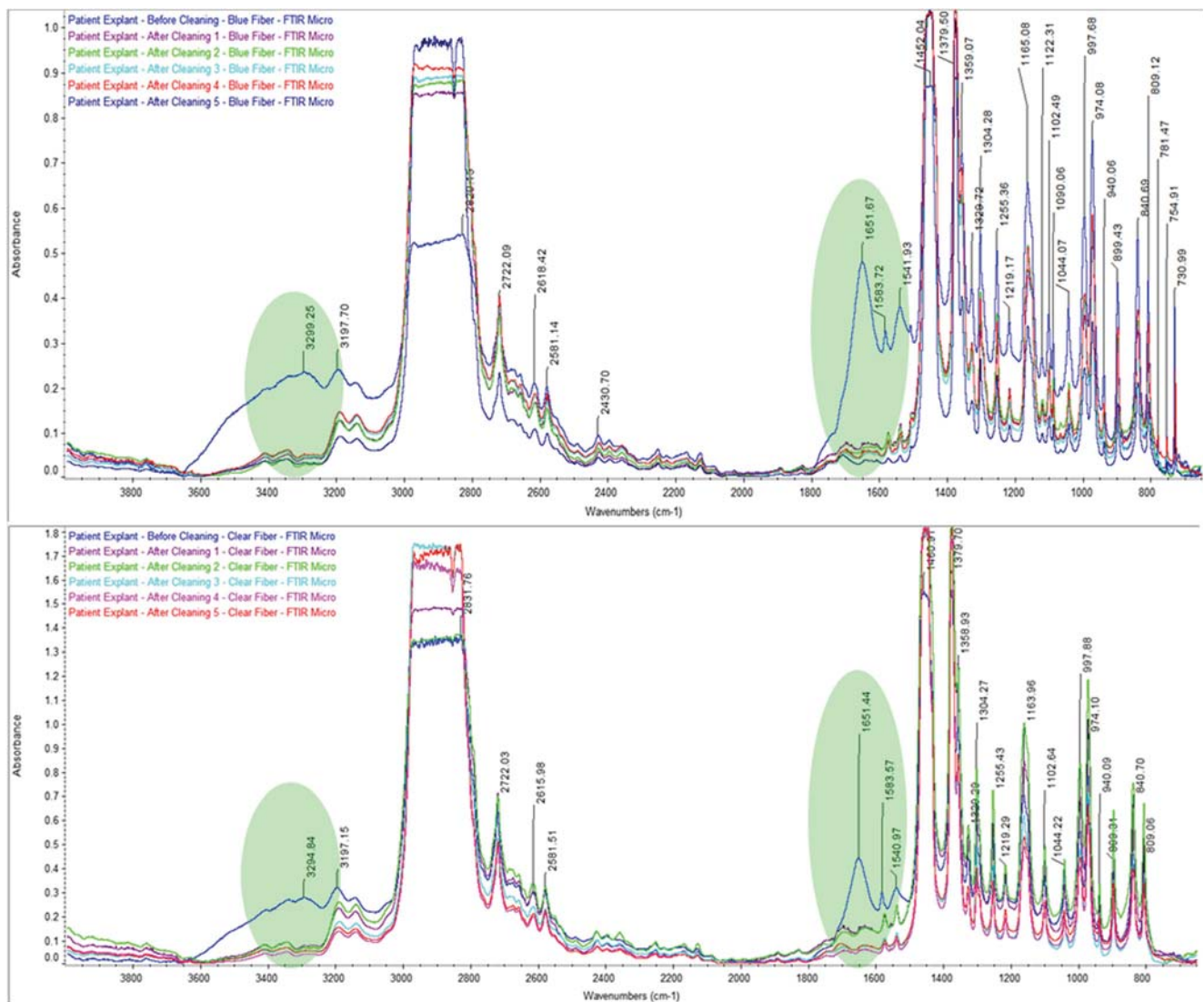


Fig. 6 FTIR of blue (*top*) and clear (*bottom*) fibers after progressive cleaning steps for Patient 033 explant, demonstrating progressive loss of proteins

tissue and biological layer appeared to be more easily removed for the explants that were received in a dry condition than those received in fixatives (Fig. 11).

Discussion

With the implementation of a novel and effective cleaning process followed by microscopy and chemical analyses, we confirmed that the explanted Prolene meshes we examined did not degrade or oxidize in vivo. FTIR absorption frequencies previously attributed by others to byproducts of oxidative degradation were observed. However, these frequencies are within the protein absorption region and are expected to be present given mesh exposure to bodily fluids, tissue ingrowth, and subsequent exposure to formalin fixatives after explantation. FTIR analyses confirmed progressive protein removal and loss of protein absorption intensity after each cleaning step.

Microscopy demonstrated progressive removal of bulk formalin fixed tissue and regions with the proteinaceous explant shell after each cleaning step. The cleaning process exposed smooth, clean, unoxidized and nondegraded fibers, with no evidence of gradient-type or ductile damage with non-uniform crack depths. Based on effective fiber cleaning and subsequent analyses, there is no evidence to support in vivo Prolene degradation.

Over the past several years, a number of researchers have claimed that PP oxidizes in vivo [5–12]. Oxidation of PP is known to result in the loss of molecular weight, deterioration of physical properties, embrittlement, chain scission, and production of carbonyl-containing byproducts [26]. In an animal study, Liebert et al. demonstrated that unprotected PP oxidizes to carbonyl compounds [19]. However, their study also found no change in the infrared spectra or tan delta of implants containing antioxidants; it was concluded that PP filaments implanted subcutaneously in hamsters degrade by an

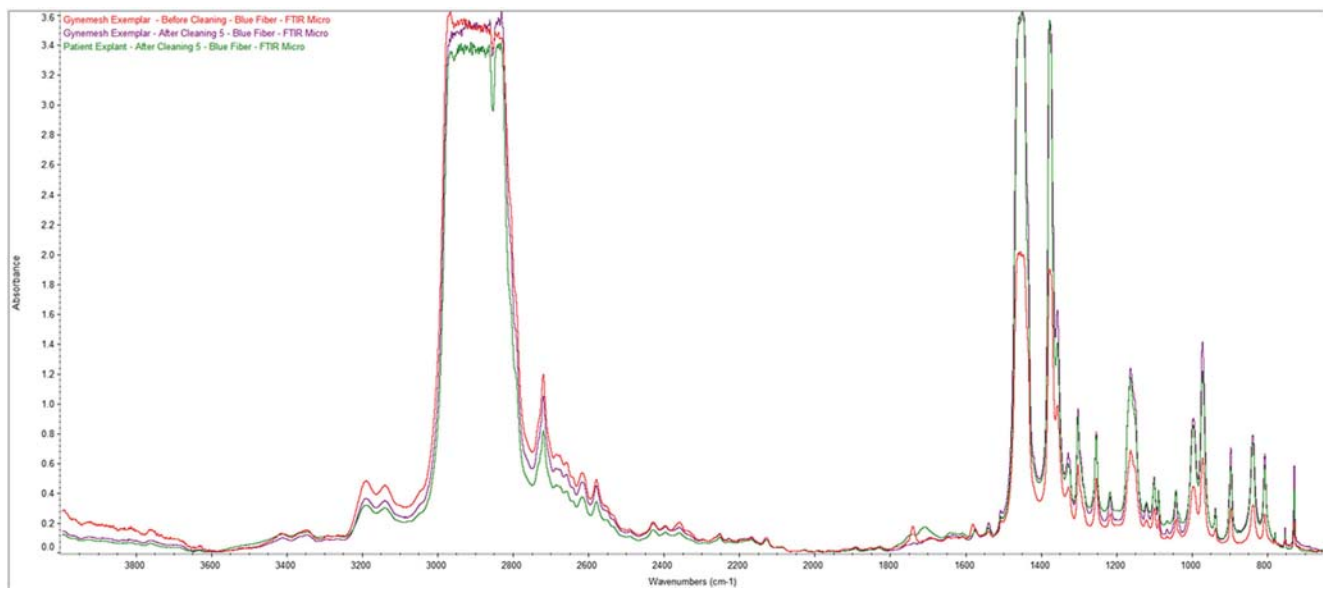


Fig. 7 Patient 033 explant and Gynemesh exemplar: FTIR of blue fibers after all the cleaning steps, illustrating overlapping spectra

oxidation process, but that the process is effectively retarded by the use of antioxidants. The authors did not observe any changes in mechanical properties or infrared spectra for any of the filaments containing antioxidants either.

Some researchers have identified cracked surfaces on explanted PP meshes and suggested that they might be a consequence of PP oxidation, although the associated compositional analysis has been limited and inconclusive [5–12]. Furthermore, these claims are based on explants whose analyses have failed to consider the effects of the fiber fixation process and the need for more effective cleaning. For example, Clavé et al. [5] has been frequently cited as supporting the notion that PP degrades in vivo. Although their manuscript title suggests that PP might not be inert, their findings clearly did not support in vivo degradation. For instance:

- DSC analyses showed that “no modification was observed in the melting temperature or heat of fusion of these samples.” Their study also reported that “no difference

between DSC thermograms of pristine and degraded samples was found.”

- Furthermore, they clearly indicated that “Several hypotheses concerning the degradation of the polypropylene are described below. None of these, particularly direct oxidation, could be confirmed in this study.”
- In addition, their “FTIR analysis neither confirmed nor excluded oxidation of PP in the in vivo environment” nor did it “conclusively confirm that the degradation was due to oxidation.”

Despite utilizing FTIR, SEM, and DSC, Clavé et al. [5] was unable to prove PP oxidation, yet continued to speak of degraded PP with no supporting data. Their observations clearly reflect artifacts from the cracked surfaces of “fixed” proteins.

Similar to Clavé et al., Costello et al. also examined formalin-fixed explanted hernia meshes [6], but used an inadequate cleaning process, which consisted only of a 2-h soak in

Fig. 8 Scanning electron microscopy micrographs from Patient 007 (*left*) and Patient 033 (*right*) before cleaning. Image magnification: $\times 1,000$ (*left*) and $\times 200$ (*right*)

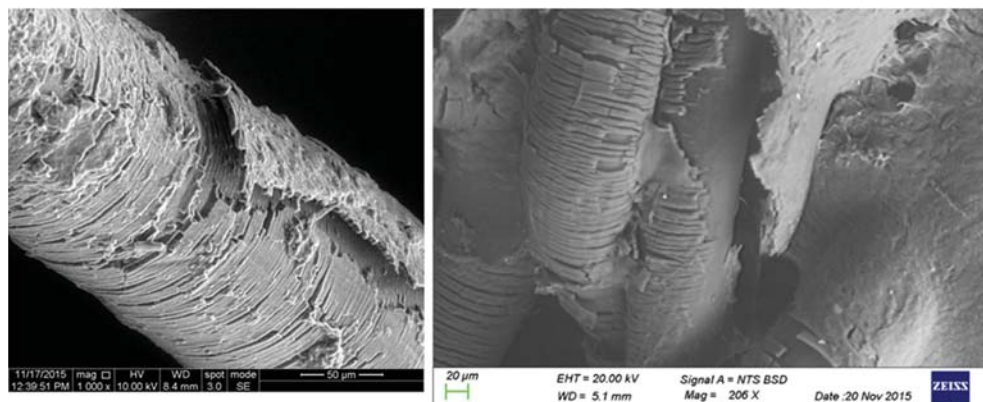


Fig. 9 Scanning electron microscopy micrographs from Patient 033 at progressive time points in the cleaning process. Images are shown for two locations: *a* (left) and *b* (right). Image magnification: $\times 500$



sodium hypochlorite at 37 °C followed by rinsing with distilled water. Our work has shown this to be an inferior and insufficient cleaning procedure that does not completely remove “formalin-fixed” tissue. Moreover, Costello et al. did not perform FTIR analyses, which would have confirmed that the explants were not free of “fixed” proteins. Iakovlev et al. [9] did not perform any elemental or chemical analyses to support their conclusions either. Imel et al. [10] also attributed cracks on explanted PP fibers to oxidized and degraded polypropylene, using the presence of nitrogen from energy dispersive spectroscopy (EDS) analyses to distinguish between biological material and polypropylene. Yet, their own EDS analyses showed the presence of nitrogen and sodium in the cracked region; these are elements consistent with biological matter, including proteins. The findings from these previous studies are also significantly affected by the lack of any/or adequate cleaning. As discussed by Imel et al. [10], all but

one of the explanted samples were rinsed in ultrapure water and allowed to air dry. Only their sample XP-11 was treated with sodium hypochlorite solution in an attempt to remove biological tissue; however, the SEM images of XP-11 still showed the presence of biological matter. The specimens prepared by Iakovlev et al. [9] were devoid of reagents used to remove tissue and biological material from the meshes before performing histological analyses. Gross tissue and biological material were still present on the mesh fibers. As we demonstrated in our study, effective cleaning of the mesh is necessary to be able to remove the remnant biological material and examine the fiber surface that is underlying the cracked layer. This allows visualization of the transition from the cracked surface layer to the bulk fiber material to determine whether a gradient of damage exists, i.e., PP crack propagation, or whether there is a distinct interface exposing smooth, clean, unoxidized, and nondegraded fibers, i.e., a biological layer

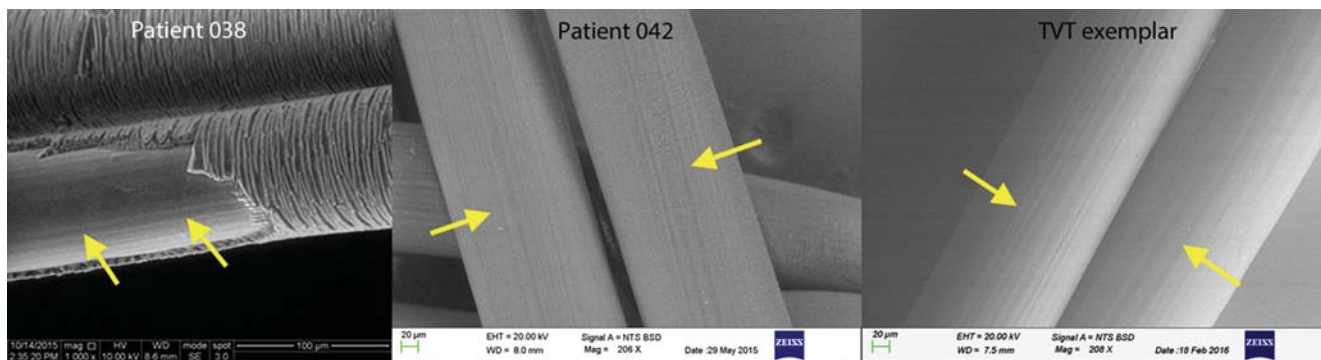


Fig. 10 The cleaning process exposed clean, unoxidized, nondegraded Prolene explant fibers with smooth surfaces and with no visible evidence of gradient-type or ductile damage. *Left* Patient 038 after cleaning sequence 1 and *middle* Patient 042 after cleaning sequence 5. The

cleaned explant fibers retained the manufacturing extrusion lines created during fiber manufacture, similar to those found with the exemplar meshes that also went through the same cleaning process. *Right* tension-free transvaginal tape after cleaning sequence 5

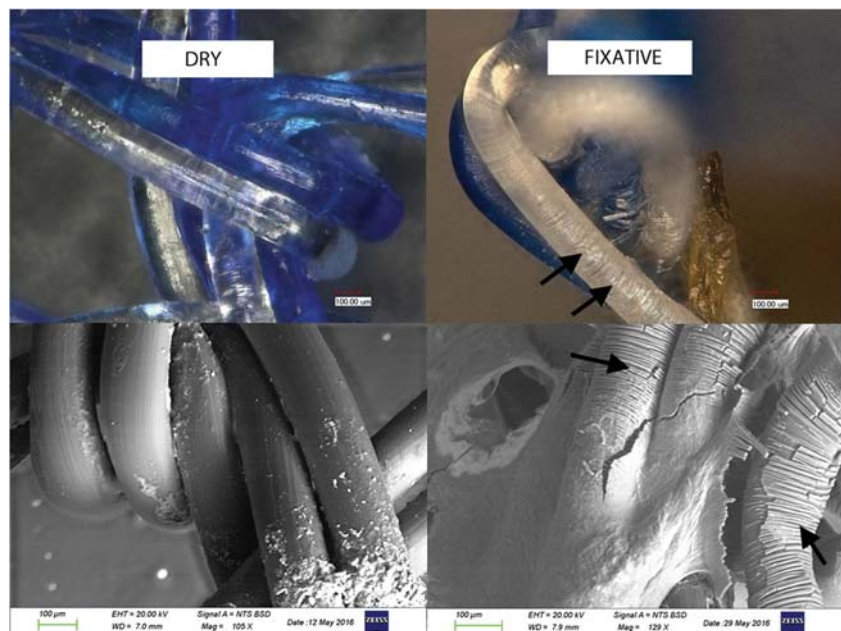
overlaying the PP fiber. Fiber pitting was not observed either. The FTIR analysis further demonstrated that the initial carbonyl absorption of proteins disappeared as proteins were removed from the fiber surface during cleaning because of their solubility in water. On the other hand, if polypropylene had oxidized to form carbonyl bonds, the newly created hydrocarbon-carbonyl product would not have been soluble in water, would thus have remained part of the explant, and would have been detected by FTIR microspectroscopy, which was not the case.

These studies failed to consider the natural adsorption of biological material when medical devices come into contact with bodily fluids, the reaction of fixatives with biological materials adsorbed onto PP, and inadequate removal of formalin-fixed proteins. Foreign body implantation elicits immediate formation of tenaciously adsorbed and adhered “protein coating(s)” onto surfaces of implanted material(s)

[13]. Almost instantaneously following implantation, proteins interact with and adhere to the biomaterial surface through protein adsorption, creating a layer of proteinaceous coating. Even before cells reach the implant, body proteins are adsorbed onto implanted material surfaces. The adsorbed proteins form an encapsulating coating around the biomaterial (implant) surface before cells arrive and begin proliferation. Consequently, cells do not come in contact with the foreign material, but with an adsorbed and adhered protein surface.

Of great significance is that explanted PP meshes are typically stored in fixatives such as formaldehyde (formalin) or glutaraldehyde following surgical explantation. The formalin fixation process involves a chemical reaction between adsorbed biological material (proteins) and formaldehyde that creates a strong bond with the mesh fiber. The strongly adhering formalin-protein fixation product is resistant to removal/digestion from fiber(s) [14, 16]. Generally, we observed that

Fig. 11 Explants from Patient 056. *Left* sample that was received dry; *right* sample that was received in fixative after cleaning sequence 1. Light microscopy images are shown at the top (magnification: $\times 200$; examples of the cracked layer are denoted by arrows; note the difference in translucency of the fibers) and scanning electron microscopy images are shown at the bottom. The cracked biological layer overlying the fibers was not as evident in the dry sample (*left*) following cleaning sequence 1 as in the fixed sample (*right*)



the tissue and biological layer appeared to be more easily removed for the explants that were received dry than those received in fixatives (Fig. 11). However, although 12 of the explants were received dry, we were unable to verify if they had been exposed to fixative at any point before we received and analyzed them.

The chemistry of formaldehyde fixation, i.e., the chemical reaction of formaldehyde with proteins, is the chemical reaction that produces “fixed tissues.” Yet this concept has been ignored or misunderstood by nonchemists when evaluating explants. Exposure to a fixative (formaldehyde) causes adsorbed proteins on mesh fibers to crosslink immediately and form a hard, brittle, protective composite layer. Fixatives are used expressly to preserve tissue and to crosslink in preparation for further study [15, 16]. A notable consequence with the use of formaldehyde, or any fixative, is the amount of distortion produced by the fixation process, which can be associated with tissue shrinkage [27]. The distortion caused by exposure to fixative can further exacerbate the effects of tissue retraction following excision, which occurs because of a loss of tension between the mesh/tissue explant and the surrounding tissue when it is excised [28, 29], thereby leading to the production of cracks in the protein coating. Previous researchers who used histological analyses to support their claims of PP degradation [13] have also failed to consider that their sample embedding processes cause tissue distortion and shrinkage [30, 31], which produces further post-excision artifacts in their analyses. Formalin fixation can also further affect chemical analysis because it can shift and alter the intensity of absorption frequencies in FTIR analysis of tissue [17]. Zhang et al. [16] notes that “In order to study the surface chemistry of explanted prostheses, it is necessary to remove all the tissue that may have grown over and within the prosthetic structure.” The author also states that the degree of crosslinking may require strong chemicals and/or extreme hydrolysis to adequately clean the fiber(s).

Based on knowledge of protein adsorption onto foreign body surfaces and the “reversible” formalin fixation reaction, we developed the mild but highly effective cleaning process that we report herein. The cleaning process involves heating “formaldehyde-fixed” bulk tissue-covered explants in excess distilled water at elevated temperatures for several hours, with the inclusion of additional steps, such as treatment with sodium hypochlorite to remove excess bulk tissue, and proteinase K to assist with removal of residual and strongly adhering, formalin-fixed proteins.

Some researchers have claimed that the mesh material degrades and speculated that this might have an impact on the clinical performance of the device, through stiffening of the mesh, decreasing the mechanical properties of the mesh, playing a role in inflammation-mediated tissue damage, and increasing the need for revision surgeries due to material incompatibility [7, 9, 10]. Yet, the claimed cracking and

degradation of the mesh have not produced any published reports of physical mesh breakage, nor have they been observed in our series of explants with implantation durations of up to 11.7 years. Furthermore, if there was indeed degradation of the Prolene material, the explants would be expected to exhibit a wide range of crack morphology in terms of non-uniform crack penetration at different locations for a given explant, and across explants from different patients, but this was not present in our study.

Questions and confusion about the clinical performance of transvaginal meshes had also arisen following the US Food and Drug Administration’s (FDA) communication on the safety and effectiveness of transvaginal meshes for pelvic organ prolapse and mesh litigation that ensued [4, 32]. However, the professional societies have recognized that polypropylene is safe and effective as a surgical implant [4], and that polypropylene midurethral sling meshes are the standard of care for the surgical treatment of stress urinary incontinence [4]. Additionally, transvaginal meshes are not only accepted, but preferred in certain clinical situations for the treatment of pelvic organ prolapse [32]. In terms of the Prolene meshes that were examined in the present study, the polypropylene monofilaments have the same composition as Prolene sutures, which have been in use since 1969. The TVT mesh dates back to 1998, when it was cleared by the FDA [3] and has shown positive results. In a randomized controlled trial comparing TVT with colposuspension in 344 women with stress incontinence, there was a higher cure rate for the TVT patients [33]. Systematic reviews of transvaginal mesh kits have also reported a mean objective success rate of 87 % for the Prolift in treating apical prolapse [34]. Randomized controlled trials have also reported a reduction in prolapse recurrence and higher anatomical success rates for Prolift compared with other treatments, such as sacrospinous fixation [35] and anterior colporrhaphy [36], although surgical and postsurgical complication rates were higher. Studies involving the Gynemesh PS mesh have also shown improvements in the quality of life and associated improvements in prolapse symptoms, with overall anatomical success rates of 88.0 % at 1 year and 66.7 % at 5 years, in addition to a net positive effect on sexual activity following prolapse surgery, despite the use of mesh [37]. Durable prolapse repairs with 80 % anatomical success rates at 3 years have also been described following the use of Gynemesh PS [38]. Although some have claimed that mesh stiffening occurs [9], Jacquetin et al. observed moderate or severe vaginal stiffness in only 12.6 % of Gynemesh PS patients after 1 year, but this rate had not increased over time at 3 years [38].

Owing to the nature of explant analysis, our study was limited to devices that were removed during revision surgeries for various clinical reasons and we were unable to analyze implants from other patients who did not undergo revision surgery or from autopsy specimens. Because of the sample

size, statistical analysis was not performed; for example, the effects of implantation time, mesh type, storage time, patient age, and storage condition were not examined for the ease of removing the biological layer, but the results and conclusions were consistent for all our specimens. We did not quantify how much of the fiber surface was covered with the cracked biological layer for each sample after each cleaning sequence. This was due to the variability in the amount of bulk tissue that was excised with the explants during resurgery, which also appeared to affect how much biological matter was removed from location to location within a given explant. Our findings are also limited to Prolene mesh and may not necessarily apply to other polypropylene formulations, because the types and concentrations of additives, particularly stabilizers, may vary among manufacturers/suppliers.

Conclusion

Adequately formulated polypropylene, in terms of having adequate in vivo stability, along with adequate types and concentrations of additives, or in this case, Prolene, is a well-accepted biomaterial with a long history of safe and effective clinical use as a permanent implant. Our effective cleaning of explanted Prolene meshes and subsequent analyses showed that they did not degrade in vivo. Instead, the cracked layer that some researchers have identified as degraded Prolene is an adsorbed protein–formaldehyde coating, resulting from the well-established formalin–protein fixation process that occurs immediately upon placing an explant in formalin.

Compliance with ethical standards

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Conflicts of interest SFT has provided litigation consulting services to Ethicon, Inc. In addition, as employees for Exponent, a science and engineering consulting company, JBW and KLO provide consulting services for a number of medical device companies. Exponent has been paid fees by such companies for their consulting services, which include both litigation and pro-active services. Exponent's client list is confidential and proprietary. However, the list of KLO's publicly disclosed consulting clients includes the following: Ethicon, Inc.; St. Jude Medical; Zimmer-Biomet; Stryker; Paradigm Spine; Medtronic; DJO; Ossur; Ferring Pharmaceuticals; Pacira Pharmaceuticals.

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